34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	201
Committee:	None

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

Clarify what information needs to be supplied to the state regulatory agency and FDA to review that a non-grade "A" dairy ingredient meets the criteria of use "for a functional or technical effect" in Definition Z of the PMO and set forth a time frame for that review.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

The dairy industry continues to innovate, with the use of new processing technologies such as filtration and ion exchange, to produce novel dairy ingredients with specific functional and technical attributes when used in food and dairy products. Some of these new dairy ingredients may not be available in a grade "A" form.

FDA has informed IDFA that they will on case-by-case basis review information supplied to them to determine that a non-grade "A" dairy ingredient is being used for a functional or technical effect in a grade "A" dairy product. FDA specified that the dairy processor would need to demonstrate with analytical measurements and organoleptic observations that the non-grade "A" specialized dairy ingredient provided a specific function or technical effect that could not be achieved when using a similar commodity-type dairy ingredient available in grade "A" form. This information would be supplied to Monica Metz, who if needed would also consult with the appropriate scientific experts at FDA and issue a determination.

IDFA believes that all stakeholders in the dairy industry and state regulators should all be fully aware of the process that FDA uses to consider if a non-grade "A" dairy ingredient provides a specific technical of functional effect in grade "A" dairy products. Additional clarification in the PMO should provide what information should be submitted to the Regulatory Agency and FDA by dairy processors and dairy ingredient manufactures. In addition a time frame for

review should also be established.

C. Proposed Solution			
Changes to be made on page(s):	6	of the (X - one of the following):	
X	2011 PMO		2011 EML
	2011 MMSR		2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

Z. **MILK PRODUCTS:** Grade "A" Milk and Milk Products include:
1. All milk and milk products with a standard of identity provided for in 21 CFR Part 131, excluding 21 CFR 131.120 Sweetened Condensed Milk.
2. Cottage cheese (21 CFR 133.128) and dry curd cottage cheese (21 CFR 131.129)2.
3. Whey and whey products as defined in 21 CFR 184.1979, 184.1979a, 184.1979b, 184.1979c, and Section 1, Definition SS of this *Ordinance*.
4. Modified versions of these foods listed above in Items 1 and 2, pursuant to 21 CFR 130.10- requirements for foods named by use of a nutrient content claim and a standardized term.
5. Milk and milk products as defined in Items 1, 2, 3 and 4 above, packaged in combination with food(s) not included in this definition that are appropriately labeled with a statement of identity to describe the food(s) in final packaged form, e.g., "cottage cheese with pineapple" and "fat free milk with plant sterols".
6. Products not included in Items 1-5 are Grade "A" milk products which have a minimum of 2.0% milk protein (Total Kjeldahl Nitrogen (TKN) X 6.38) and a minimum of sixty-five percent (65%) by weight milk, milk product or a combination of milk products.

Safe and suitable (as defined in 21 CFR 130.3(d)) non-grade “A” dairy ingredients, can be utilized in the products defined in Items 1-6 when added to a level needed for a functional or technical effect, and limited by Good Manufacturing Practices (GMPs) and are either:
a. Prior sanctioned or otherwise approved by FDA, or
b. GRAS (generally recognized as safe), or
c. An approved food additive listed in the CFR.
Except that with respect to those products which have a federal standard of identity, only ingredients provided for in the standard may be utilized.

NOTE: Non-grade “A” dairy ingredients can be used once the Regulatory Agency has reviewed and accepted information, in consultation with FDA, supporting that the use is to achieve a functional or technical effect in the finished product. Supporting information shall be submitted by the dairy processor and/or the ingredient manufacturer for review and approval by the Regulatory Agency and FDA prior to manufacturing and selling the finished product. The proposal shall be deemed approved unless denied within 90 days of receipt of the submission to the Regulatory Agency and FDA. Any significant formulation or processing changes shall be communicated to the Regulatory Agency, and may result in resubmission of the supporting data, if it is determined that the change could potentially affect the safety of the

finished milk or milk product(s).
The supporting information may include but is not limited to:
a. Statement of proposal for usage of a non-grade “A” dairy ingredient.
b. Finished Product description
c. Non-grade “A” dairy ingredient description and usage level
d. Analytical measurements and organoleptic observations that the non-grade “A” dairy ingredient provides a specific function or technical effect that could not be achieved when using a similar commodity-type dairy ingredient available in grade “A” form.

When a non-grade "A" dairy ingredient is used to increase weight or volume of the product, or displace grade "A" dairy ingredients, this use is not a suitable functional or technical effect.

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34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	202
Committee:	None

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This proposal affirms that products purporting to be or are labeled as milk or milk products shall be produced according to all the standards contained in the *PMO*.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

The milk sanitation program of the United States Public Health Service (USPHS) is one of its oldest and most respected activities. The model milk regulations upon which the current PMO is based have a nearly 100-year history, which is directly responsible for the renowned food safety success of the industry and the "dairy halo" – pasteurized milk and fluid milk products continue to be associated with less than one percent (<1%) of such reported outbreaks (2011 PMO).

Through the continuous efforts by the dairy industry and public health agencies to improve the food safety of the milk supply, US consumers readily recognize milk and other milk products to be among the safest foods available.

C. Proposed Solution

Changes to be made on page(s): 6 of the (X - one of the following):

X	2011 PMO		2011 EML
	2011 MMSR		2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

Z. **MILK PRODUCTS:**

Grade "A" Milk and Milk Products shall be produced according to the sanitary standards of this *Ordinance*.

Grade "A" Milk and Milk Products include:

1. All milk and milk products with a standard of identity provided for in 21 CFR Part 131, excluding 21 CFR 131.120 Sweetened Condensed Milk, or that are labeled as such.

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34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	203
Committee:	None

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

To clarify the pasteurization time and temperature charts in the PMO in relation to the type of pasteurization equipment utilized.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

People unfamiliar with pasteurization equipment refer to the charts in the PMO that indicate the required time and temperature combinations for legal pasteurization of milk and milk products and mistakenly assume that any of the combinations will work with batch pasteurization. Identifying the types of pasteurization systems that can utilize the time and temperature combinations should alleviate any misconceptions.

C. Proposed Solution

Changes to be made on page(s): 8, 9, and 83 of the (X - one of the following):

X	2011 PMO		2011 EML
	2011 MMSR		2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

Modify page 8 of the 2011 PMO, Section 1, Definition HH, chart.

Temperature	**Time**
Batch (Vat) Pasteurization	
63ºC (145ºF)*	30 minutes
Continuous Flow (HTST, HHST) Pasteurization	
72ºC (161ºF)*	15 seconds
89ºC (191ºF)	1.0 second
90ºC (194ºF)	0.5 seconds
94ºC (201ºF)	0.1 seconds
96ºC (204ºF)	0.05 seconds
100ºC (212ºF)	0.01 seconds

Modify page 9 of the 2011 PMO, Section 1, Definition HH, chart.

Temperature	**Time**
Batch (Vat) Pasteurization	
69ºC (155ºF)	30 minutes
Continuous Flow (HTST. HHST) Pasteurization	
80ºC (175ºF)	25 seconds
83ºC (180ºF)	15 seconds

Modify page 83 of the 2011 PMO, item 16p, Administrative Procedures, Table 3.

Temperature	**Time**
Batch (Vat) Pasteurization	
63ºC (145ºF)*	30 minutes
Continuous Flow (HTST, HHST)	

Pasteurization	
72ºC (161ºF)*	15 seconds
89ºC (191ºF)	1.0 second
90ºC (194ºF)	0.5 seconds
94ºC (201ºF)	0.1 seconds
96ºC (204ºF)	0.05 seconds
100ºC (212ºF)	0.01 seconds

Modify page 83 of the 2011 PMO, item 16p, Administrative Procedures, chart.

Temperature	**Time**
Batch (Vat) Pasteurization	
69ºC (155ºF)	30 minutes
Continuous Flow (HTST. HHST) Pasteurization	
80ºC (175ºF)	25 seconds
83ºC (180ºF)	15 seconds

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34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	204
Committee:	None

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

To remove standard requiring a label on condensed or dry milk products that identifies the Regulatory Agency responsible for issuing the permit.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Section 4 *Labeling* of the 2011 Pasteurized Milk Ordinance (PMO) requires the identity of the Regulatory Agency that issues the permit to be placed on labels for condensed or dry milk products. While this information is important to know and can be obtained by accessing the Interstate Milk Shippers list, it is unknown why condensed and dry milk products are singled out. No other milk or milk products are required to identify the Regulatory Agency directly on the label. Compliance with this standard, based on inspections and state ratings, has shown to be lacking in several instances.

It is far more important to consumers and the public that the identity of the plant, as currently required by the 2011 PMO, be disclosed on a label rather than the identity of the Regulatory Agency. By requiring extra type and ink such as "Virginia Department of Health" (26 characters), it can also add indirect cost to the product as well as limit the amount of space available on the label for other information. This proposal seeks to eliminate a burdensome requirement that duplicates information already available on the Interstate Milk Shippers list.

C. Proposed Solution

Changes to be made on page(s):	p.15	of the (X - one of the following):	
X	2011 PMO		2011 EML
	2011 MMSR		2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

MAKE THE FOLLOWING CHANGES TO THE 2011 PMO:

Modify the 2011 PMO, p.15, Section 4, Labeling, item 6a as follows:

6. In the case of condensed or dry milk products the following shall also apply:

a. ~~The identity of the Regulatory Agency issuing such permit;~~ and if distributed by another party, the name and address of the distributor shall be shown by a statement, such as "Distributed by".

b. A code or lot number identifying the contents with a specific date, run, or batch of the product, and the quantity of the contents of the container.

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34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	205
Committee:	None

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

To remove the PMO Section 4. Item 6.a. requirement for the identity of the regulatory agency on containers of condensed and dry milk products.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

The labeling provisions of the PMO (Section 4., Item 6.) require that condensed and dry milk products be labeled with the identity of the Regulatory Agency issuing the permit for their production. This provision is unnecessary, and the requirement is not being uniformly enforced.

Item 1. of the same section already requires that the identity of the milk plant where these products are condensed and/or dried be specified. The existing provisions for designating condensed and/or dry milk products as Grade "A" (if applicable) , providing the identification of the milk plant where these products were condensed and/or dried, and including a properly completed shipping statement for bulk condensed loads provide adequate identification and traceability for these products.

C. Proposed Solution

Changes to be made on page(s): 15 of the (X - one of the following):

X	2011 PMO		2011 EML
	2011 MMSR		2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

Modify the 2011 PMO, Page 15, Section 4., item 6.a.

6. In the case of condensed or dry milk products the following shall also apply:
   a. The identity of the ~~Regulatory Agency issuing such permit~~ milk plant where condensed and/or dried; and if distributed by another party, the name and address of the distributor shall also be shown by a statement, such as "Distributed by".

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34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	206
Committee:	MMSR

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This Proposal provides consistency and uniform wording in the PMO and MMSR in relationship to determining the inspection frequency for bulk milk hauler/samplers, industry samplers and dairy plant samplers.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

In the PMO and MMSR, there are specific citations providing guidance for determining the inspection frequency for dairy farms, milk plants, receiving stations and transfer stations. This Proposal provides similar wording to be added to the two (2) documents for determining the inspection frequency for bulk milk hauler/samplers, industry samplers and dairy plant samplers.

C. Proposed Solution

Changes to be made on page(s): PMO-19 & 130 and MMSR-94 of the (X - one of the following):

X	2011 PMO		2011 EML
X	2011 MMSR		2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

MAKE THE FOLLOWING CHANGES TO THE 2011 PMO:

~~Strike through~~ text to be deleted and underline text to be added.

SECTION 5. INSPECTIONOF DAIRY FARMS AND MILK PLANTS

Page 19

ADMINISTRATIVE PROCEDURES

INSPECTION FREQUENCY: For the purposes of determining the inspection frequency for dairy farms, transfer stations and milk plants or the portion of a milk plant that is IMS listed to produce aseptically processed and packaged milk or milk products, the interval shall include the designated six (6) month period plus the remaining days of the month in which the inspection is due

For the purposes of determining the inspection frequency for all other milk plants and receiving stations, the interval shall include the designated three (3) month period plus the remaining days of the month in which the inspection is due.

For the purposes of determining the inspection frequency for bulk milk hauler/samplers, industry plant samplers and dairy plant samplers, the interval shall include the designated twenty-four (24) month period plus the remaining days of the month in which the inspection is due. …

Page 130:

APPENDIX B. MILK SAMPLING, HAULING AND TRANSPORTATION

I. MILK SAMPLING AND HAULING PROCEDURES …

The industry plant sampler or bulk milk hauler/sampler is a person responsible for the collection of official samples for regulatory purposes at a milk plant, receiving station, or transfer station as outlined in Appendix N. These industry plant samplers are employees of the dairy plant, receiving station or transfer station and are evaluated at least once each two (2) year period by a SSO or a properly delegated Sampling Surveillance Regulatory Official. These industry plant samplers are evaluated using FORM FDA 2399-MILK SAMPLE COLLECTOR EVALUATION REPORT (Dairy Plant Sampling – Raw and Pasteurized Milk), which is derived from the most current edition of *SMEDP*. (Refer to Appendix M.)

NOTE: For the purposes of determining the inspection frequency for bulk milk hauler/samplers, industry plant samplers and dairy plant samplers, the interval shall include the designated twenty-four (24) month period plus the remaining days of the month in which the inspection is due. ….

MAKE THE FOLLOWING CHANGES TO THE 2011 MMSR:

~~Strike through~~ text to be deleted and underline text to be added.

GUIDANCE FOR COMPUTING ENFORCEMENT CREDIT FOR PART I, ITEM 9

34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	207
Committee:	Lab/MMSR

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

With the passage of M-a-98 (Official *Grade "A" Pasteurized Milk Ordinance* (PMO) Regulatory Laboratory Tests For Grade "A" Milk And Milk Products And Grade "A" Dairy Farm And Milk Plant Water), appropriate references citing M-a-98 are proposed to be added to the PMO and the MMSR.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

By referencing M-a-98 in the PMO and the MMSR it will provide a means to determine what laboratory test methods have been validated by FDA and accepted by the NCIMS and; therefore, are to be utilized for the specific milk matrix when such testing is required within the PMO.

C. Proposed Solution

Changes to be made on page(s): PMO-23-27, 29, 30, 214, 216, 217 & 354; MMSR-11 & 88 of the (X - one of the following):

X	2011 PMO		2011 EML
X	2011 MMSR		2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

MAKE THE FOLLOWING CHANGES TO THE 2011 PMO:

~~Strike through~~ text to be deleted and underline text to be added.

Page 23:

SECTION 6. THE EXAMINATION OF MILK AND MILK PRODUCTS

3. During any consecutive six (6) months, at least four (4) samples of pasteurized milk, ultra-pasteurized milk, flavored milk, flavored reduced fat or low fat milk, flavored nonfat (skim) milk, each fat level of reduced fat or low fat milk and each milk product defined in this *Ordinance*, shall be collected by the Regulatory Agency in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days from every milk plant. All pasteurized and ultra-pasteurized milk and milk products required sampling and testing is to be ~~done~~ conducted only when there are test methods available that are validated by FDA and accepted by the NCIMS. ~~Products with no~~ Milk and/or milk products that do not have validated and accepted methods are not required to be tested. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods.) Aseptically processed and packaged milk and milk products shall be exempt from the sampling and testing requirements of this Item. …

Page 24:

All pasteurized and ultra-pasteurized milk and milk products required sampling and testing to be done only when there are test methods available that are validated by FDA and accepted by the NCIMS, otherwise there would ~~be no~~ not be a requirement for sampling. Required bacterial counts, coliform counts, drug tests, phosphatase and cooling temperature determinations shall be performed on Grade "A" pasteurized and ultra-pasteurized milk and milk products defined in this *Ordinance* only when there are validated and accepted test methodology. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods.) …

Page 25:

Assays of milk and/or milk products as defined in this *Ordinance*, including aseptically processed and packaged milk and/or milk products, to which vitamin(s) A and/or D have been added for fortification purposes, shall be ~~made~~ conducted at least annually in a laboratory, which has been accredited by FDA and which is acceptable to the Regulatory Agency, using test methods acceptable to FDA or other official methodologies, which gives statistically equivalent results to the FDA methods. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods for vitamins.) Vitamin testing laboratories are accredited if they have one (1) or more certified analysts and meet the quality control requirements of the program established by FDA. Laboratory accreditation and analyst certification parameters are specified in the Evaluation of Milk Laboratories (EML) manual. …

Page 26:

3. Coliform test with solid media or Petrifilm method at 32ºC ~~for all milk and milk products,~~ and the Petrifilm High Sensitivity Coliform Count method for all milk and milk products~~, except unflavored whole, reduced or low fat and nonfat (skim) milk~~.

5. Beta lactam methods which have been independently evaluated or evaluated by FDA and have been found acceptable by FDA and the NCIMS for detecting Beta lactam drug residues in raw milk, or pasteurized milk, or ~~that~~ a particular type of pasteurized milk product at current safe or tolerance levels, shall be used for each Beta lactam drug of concern~~,~~. ~~except~~ This does not apply to those milk products for which there are not any approved Beta lactam drug test kits available. (Refer to M-a-85, latest revision, for the approved drug tests and M-a-98, latest revision, for the specific milk and/or milk product for which there are approved drug tests available.) Regulatory action shall be taken on all confirmed positive Beta lactam results. (Refer to Appendix N.) A result shall be considered positive for Beta lactam if it has been obtained by using a method, which has been evaluated and deemed acceptable by FDA and accepted by the NCIMS at levels established in memoranda transmitted periodically by FDA as required by Section IV of Appendix N.

Page 27:

NOTE: Milk from animals not currently in the *Grade "A" PMO* may be labeled as Grade "A" and IMS listed upon FDA's acceptance of validated *Grade "A" PMO,* Section 6 and Appendix N. test methods for the animal to be added. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods) …

Pages 29 and 30:

Table 1. Chemical, Physical, Bacteriological, and Temperature Standards
(Refer to M-a-98, Latest Revision, for FDA Validated and NCIMS Accepted Tests Methods.) …

GRADE "A" PASTEURIZED MILK AND MILK PRODUCTS	Temperature ……..	Cooled to …..
	Bacterial Limits**..	Not to exceed….
	Coliform ……	Not to exceed….
	Phosphatase ****.. **(Delete last two *s)**	Less than ….
	Drugs**** ……..	No positive results on drug residue detection methods as referenced in Section 6-Laboratory Techniques which have been found to be acceptable for use with ~~pasteurized~~ Pasteurized ~~milk~~ Milk and/or ~~milk products~~ Milk Products. (Refer to M-a-98, latest revision.)
GRADE "A" ULTRA-	Temperature ……..	Cooled to 7°C (45°F) or less and

PASTEURIZED (UP) MILK AND MILK PRODUCTS		maintained thereat
	Bacterial Limits**...	Not to exceed 20,000 per mL, or gm*** **NOTE:** Tested in conjunction with the drug residue/inhibitory substance test,
	Coliform ……	Not to exceed 10 per mL. Provided, that in the case of bulk milk transport tank shipments, shall not exceed 100 per mL.
	~~Phosphatase****…~~	~~Phosphatase testing of UP milks is not required~~
	Drugs****…….	~~There are no validated and accepted drug residue tests for Ultra-Pasteurized Milk and Milk Products~~ No positive results on drug residue detection methods as referenced in Section 6-Laboratory Techniques which have been found to be acceptable for use with Ultra-Pasteurized Milk and/or Milk Products. (Refer to M-a-98, latest revision.)

...

* Goat Milk 1,500,000/mL

** Not applicable to acidified or cultured milk and/or milk products, eggnog, ~~and~~ ~~flavored (non-chocolate) milk and milk products~~ cottage cheese, and other milk and/or milk products as identified in the latest revision of M-a-98.

*** Results of the analysis of dairy products which are weighed in order to be analyzed will be reported in # per gm. (Refer to the current edition of the *SMEDP*.)

**** Not applicable to ~~UP products that have been thermally processed at or above 138^{0}C (280^{0}F) for at least two (2) seconds to produce a product which has an extended shelf life (ESL) under refrigerated conditions; and condensed products~~ acidified or cultured milk and/or milk products, eggnog, cottage cheese, pasteurized and ultra-pasteurized flavored (non-chocolate) milk and/or milk products and other milk and/or milk products as identified in the latest revision of M-a-98.

Page 214:

APPENDIX G. CHECMICAL AND BACTERIOLOGICAL TESTS

I. PRIVATE WATER SUPPLIES AND RECIRCULATED WAER – BACTERIOLOGICAL ..

Apparatus, Methods and Procedure: Tests performed shall conform with the current edition of *SMEWW* or with FDA approved, EPA promulgated methods for the examination of water and waste water or the applicable FDA 2400 Series Forms. (Refer to M-a-98, latest revision.)

…

Page 216:

V. DETECTION OF DRUG RESIDUES IN MILK …

The allergenic properties of certain drugs in common use make their presence in milk potentially hazardous to consumers. Also, substantial losses of byproducts may be sustained by the milk industry each year because of the inhibitory effects of drug residues on the culturing process. Drug residues shall be tested for, using tests provided for in Section 6 of this *Ordinance*. These tests are specified in memoranda from the FDA. (Refer to the latest ~~edition~~ revision of M-a-85 for the approved drug tests, ~~and~~ the FDA 2400 Series Forms for each specific test method and M-a-98, latest revision, for the specific milk and/or milk products for which there are approved drug tests available.)

Page 217:

VI. ANALYSIS OF MILK AND MILK PRODUCTS FOR VITAMIN A AND D CONTENT …

Methods: Vitamin testing shall be performed using test methods acceptable to FDA and other official methodologies that give statistically equivalent results to the FDA methods. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods for vitamins.) …

APPENDIX O. VITAMIN FORTIFICATION OF FLUID MILK PRODUCTS

Page 354:

TESTING METHODS

Test methods used for the detection of vitamins A and/or D shall be acceptable to FDA or other official methodologies that give statistically equivalent results to the FDA methods. Vitamin analysis shall be conducted in a laboratory accredited by FDA and acceptable to the Regulatory Agency. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods for vitamins.) …

MAKE THE FOLLOWING CHANGES TO THE 2011 MMSR:

Page 11:

b. Recording of Laboratory and Other Test Data …

1.) Regulatory Agency records are used in determining compliance with bacterial, coliform, phosphatase, drug residue, and cooling temperature requirements. The acceptance of data from official or officially designated laboratories is contingent upon

the utilization of standard procedures by the laboratories concerned. Accordingly, it is necessary for the SRO to determine from the official State Laboratory Certifying Agency that both sampling and laboratory procedures have been approved in accordance with the methods of the current edition of the *EML*. Ratings and HACCP listing audits shall not be conducted when an approved laboratory has not been utilized by the Regulatory Agency for the necessary tests. …

3.) The SRO may utilize Regulatory Agency's records in determining compliance with those Items of sanitation, which require laboratory tests to complete the evaluation. Official records of Equipment Tests may also be used in lieu of performing such Equipment Tests during the rating. Provided, that the SRO is satisfied as to the competency of the Regulatory Agency's personnel to perform these Equipment Tests as described in Appendix I. of the *Grade "A" PMO.*

NOTE: All pasteurized and ultra-pasteurized milk and/or milk products required sampling and testing is to be conducted only when there are test methods available that are validated by FDA and accepted by the NCIMS. ~~Products~~ Milk products that do not have validated and accepted methods are not required to be tested. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods.)
The sampling and testing of aseptically processed and packaged Grade "A" milk and/or milk products is not required, with the exception of the annual vitamin assay analysis to which vitamin(s) A and/or D have been added for fortification purposes. The sampling and testing requirements of Section 6 of the *Grade "A" PMO* for raw milk for aseptic processing and packaging is required.

Page 88:

7. Samples of each milk plant's milk and/or milk products collected at the required frequency and all necessary laboratory examinations made (*Grade "A" PMO,* Section 6 - THE EXAMINATION OF MILK AND MILK PRODUCTS). Prorate by the number of products in compliance. (Refer to M-a-98, latest revision, for the FDA validated and NCIMS accepted test methods for the specific milk and/or milk products.) …

c. All required examinations performed on each sample (bacterial, coliform, drug residue, phosphatase, and cooling temperature) in an official or officially designated laboratory.

NOTE: All pasteurized and ultra-pasteurized milk and/or milk products required sampling and testing is to be conducted only when there are test methods available that are validated by FDA and accepted by the NCIMS. Milk and/or milk products that do not have validated and accepted methods are not required to be tested. ((Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods.)

d. Assays of Vitamin A, D, and/or A and D fortified milk and milk products, including aseptically processed and packaged milk and milk products, ~~made~~ conducted at least annually in an IMS Listed Laboratory. Credit for vitamin-fortified products is not given unless vitamin analysis is completed and records are available. Each vitamin fortified

product is evaluated separately. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods for vitamins.) …

NOTE: *This Proposal shall take immediate effect upon the issuance of the IMS-a, Actions from the 2013 National Conference on Interstate Milk Shipments, following FDA's concurrence with the NCIMS Executive Board.*

Name: CFSAN

Agency/Organization: Food and Drug Administration

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34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	208
Committee:	Appendix N

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This Proposal provides clarification and corrections to Section 6-The Examination of Milk and Milk Products related to drug residue testing and Appendix N-Drug Residue Testing and Farm Surveillance of the PMO. A clarification is also made to make it clear that raw milk received at a milk plant in a manner other than on bulk milk pickup tankers is required to be tested for Beta lactam drug residues prior to processing.

Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

FDA's Milk Safety Team has received enquiries from States and milk plants related to the PMO requirements for the testing of raw milk sources prior to processing. The current wording in the PMO addresses the testing of bulk milk pickup tankers prior to processing at the receiving milk facility. This has created confusion and objection from States and milk plants that only receive their raw milk supply in a manner other than on bulk milk pickup tankers.

This Proposal follows FDA's guidance and interpretation of Appendix N that all raw milk for processing, no matter how it is received at the milk plant for processing, is required to be tested for drug residues by the milk plant prior to processing.

C. Proposed Solution			
Changes to be made on page(s):	23-27 and 342-351	of the (X – one of the following):	
X	2011 PMO		2011 EML
	2011 MMSR		2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

MAKE THE FOLLOWING CHANGES TO THE 2011 PMO.

~~Strike through~~ text to be deleted and underline text to be added.

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SECTION 6. THE EXAMINATION OF MILK AND MILK PRODUCTS …

It shall be the responsibility of the industry plant sampler to collect a representative sample of milk ~~from each milk tank truck or from a properly installed and operated aseptic sampler, which is approved for use by the Regulatory Agency and FDA to collect representative samples, prior to transferring milk from a milk tank truck.~~ for Appendix N testing from the following:

1. Each milk tank truck or from a properly installed and operated aseptic sampler, which is approved for use by the Regulatory Agency and FDA to collect representative samples, prior to transferring milk from a milk tank truck; and/or
2. Each raw milk supply that has not been transported in bulk milk pickup tankers or from a properly installed and operated in-line sampler or aseptic sampler, which is approved for use by the Regulatory Agency and FDA to collect representative samples, prior to transferring the milk from a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. for processing at that location.

~~1.~~ During any consecutive six (6) months, at least four (4) samples of raw milk …

~~2.~~ During any consecutive six (6) months, at least four (4) samples of raw milk …

~~3.~~ During any consecutive six (6) months, at least four (4) samples of pasteurized milk, …

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Whenever a pesticide residue test is positive, an investigation shall be made to determine the cause and the cause shall be corrected. An additional sample shall be taken and tested for pesticide residues and ~~no~~ milk and/or milk products as defined in this *Ordinance* shall not be offered for sale until it is shown by a subsequent sample to be free of pesticide residues or below the actionable levels established for such residues.
Whenever a drug residue test is confirmed positive, regardless of the drug(s) being tested for

or the test(s) being used, an investigation shall be made to determine the cause, and the cause shall be corrected in accordance with the provisions of Appendix N. …

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Each milk plant regulated under the NCIMS voluntary HACCP Program shall adequately document its response to each regulatory sample test result that exceeds any maximum level specified in Section 7 of this *Ordinance*. The Regulatory Agency ~~will~~ shall monitor and verify that appropriate action(s) was taken by the milk plant.
Examinations and tests to detect adulterants, including pesticides, shall be conducted, as the Regulatory Agency requires. When the Commissioner of the FDA determines that a potential problem exists with animal drug residues or other contaminants in the milk supply, samples shall be analyzed for the contaminant by a method(s) determined by FDA to be effective in determining compliance with actionable levels or established tolerances. This testing ~~will~~ shall continue until such time that the Commissioner of the FDA is reasonably assured that the problem has been corrected. The determination of a problem is to be based upon: …

Assays of milk and/or milk products as defined in this *Ordinance*, including aseptically processed and packaged milk and/or milk products, to which vitamin(s) A and/or D have been added for fortification purposes, shall be ~~made~~ conducted at least annually in a laboratory, which has been accredited by FDA and which is acceptable to the Regulatory Agency, using test methods acceptable to FDA or other official methodologies, which gives statistically equivalent results to the FDA methods. Vitamin testing laboratories are accredited if they have one (1) or more certified analysts and meet the quality control requirements of the program established by FDA. Laboratory accreditation and analyst certification parameters are specified in the Evaluation of Milk Laboratories (EML) manual.
In addition, all ~~facilities~~ milk plants fortifying milk and/or milk products with vitamins ~~must~~ shall keep volume control records. These volume control records ~~must~~ shall cross reference the form and amount of vitamin D, vitamin A and/or vitamins A and D used with the amount of milk and/or milk products produced and indicate a percent of expected use, plus or minus.

ADMINISTRATIVE PROCEDURES …

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5. Drug Testing: Beta lactam methods which have been independently evaluated or evaluated by FDA and have been found acceptable by FDA and the NCIMS for detecting Beta lactam drug residues in raw milk, or pasteurized milk, or ~~that~~ a particular type of pasteurized milk product at current safe or tolerance levels, shall be used for each Beta lactam drug of concern~~;~~. ~~except~~ This does not apply to those milk products for which there are not any approved Beta lactam drug test kits available. (Refer to M-a-85, latest revision, for the approved Beta lactam drug tests.) Regulatory action shall be taken on all confirmed Beta lactam positive results. (Refer to Appendix N.) A result shall be considered positive for Beta lactam if it has been obtained by using a method, which has been evaluated and deemed acceptable by FDA and accepted by the NCIMS at levels established in memoranda transmitted periodically by FDA as required by Section IV of Appendix N.
Once a drug test(s) for a particular drug or drug family, other than Beta lactams, has been independently evaluated, or evaluated by FDA, and has been found acceptable by FDA and the

NCIMS, only those accepted drug tests shall be used for detecting the particular drug or drug family residues in raw milk, or pasteurized milk, or a particular type of pasteurized milk product at current safe or tolerance levels. This does not apply to those milk products for which there are not any approved drug test kits available for a particular drug or drug family. (Refer to M-a-85, latest revision, for the approved drug tests.) Regulatory action shall be taken on all confirmed positive results. (Refer to Appendix N.) A result shall be considered positive if it has been obtained by using a method, which has been evaluated and deemed acceptable by FDA and accepted by the NCIMS at levels established in memoranda transmitted periodically by FDA as required by Section IV of Appendix N.

NOTE: One (1) year after a drug test(s) has been evaluated by FDA and accepted by the NCIMS for a particular drug or drug family, other unevaluated drug tests for that particular drug or drug family are not acceptable for screening milk by industry. The acceptance of evaluated drug tests by FDA and the NCIMS for drugs other than Beta lactams does not mandate any additional screening by industry or Regulatory Agencies with the evaluated test, unless it is determined by the Commissioner of FDA that a potential problem exists with other animal drug residues in the milk supply.

If industry chooses to test for a particular drug or drug family using a test kit that has not been evaluated and deemed acceptable by FDA and accepted by the NCIMS, the initial positive result shall be used to determine that the farm raw milk, milk in a bulk milk pickup tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers, or pasteurized milk or milk product is confirmed positive and considered adulterated within the meaning and context of this *Ordinance*. (Refer to M-a-85, latest revision, for the accepted and approved drug tests.) The Industry responsibilities/requirements as cited in Appendix N relating to the required reporting to the Regulatory Agency, record keeping, producer trace back, if applicable, etc. shall be followed. (Refer to Appendix N.)

6. Screening and Confirmatory Methods for the Detection of Abnormal Milk: The results of the screening test or confirmatory test shall be recorded on the official records of the dairy farm and a copy of the results sent to the milk producer.
When a warning letter has been sent, because of excessively high somatic cell counts, an official inspection of the dairy farm should be made by regulatory personnel or certified industry personnel. This inspection should be made during milking time. …

b. Goat Milk: Direct Microscopic Somatic Cell Count or Electronic Somatic Cell Count may be used for screening raw goat milk samples, to indicate a range of somatic cell levels, as long as the somatic cell standard for goat milk remains 1,500,000/mL. Screening for official purposes ~~must~~ shall be conducted by an analyst (s) certified for that procedure.
Only the Pyronine Y-Methyl Green stain or "New York modification" Single Strip Direct Microscopic Somatic Cell Count test procedures shall be used to confirm the level of somatic cells in goat milk by certified analysts.
c. Sheep Milk: Any of the following confirmatory or screening test procedures shall be used: Single Strip Direct Microscopic Somatic Cell Count or Electronic Somatic Cell Count. When results from the Single Strip Direct Microscopic Somatic Cell Count procedure exceed the 750,000/mL standard set forth in this *Ordinance*, the count ~~must~~ shall have been derived from, or be confirmed by, the Pyronine Y Methyl-Green Stain or the "New York modification". …

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10. All standards used in the development and use of drug residue detection methods designed for *Grade "A" PMO* monitoring programs ~~will~~ shall be referenced to a United States Pharmacopeia (USP) standard when available. When a USP standard is not available, then the original method ~~must~~ shall define the standard to be used.
11. Procedural or reagent changes for official tests ~~must~~ shall be submitted to FDA for acceptance prior to being used by certified NCIMS milk laboratories.

SAMPLING PROCEDURES: *SMEDP* contains guidance for the sampling of milk and milk products. Optionally, sample collection time may be identified in military time (24 hour clock). (Refer to Appendix G. for a reference to drug residues in milk and/or milk products and the conditions under which a positive phosphatase reaction may be encountered in properly pasteurized milk or cream. Refer to Appendix B. for reference to farm bulk milk hauling programs regarding training, licensing/permitting, routine inspection and the evaluation of sampling procedures.)
When samples of raw milk for pasteurization are taken at a milk plant prior to pasteurization, they shall be drawn following adequate agitation from randomly selected storage tanks/silos. All counts and temperatures ~~should~~ shall be recorded on a milk-ledger form as soon as reported by the laboratory. A computer or other information retrieval system may be used. …

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APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE

I. INDUSTRY RESPONSIBILITIES

MONITORING AND SURVEILLANCE:

Industry shall screen all bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers, regardless of final use, for Beta lactam drug residues. Additionally, other drug residues shall be screened for by employing a random sampling program on bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers when the Commissioner of the FDA determines that a potential problem exists as cited in Section 6 of this *Ordinance*. The random bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers sampling program shall represent and include, during any consecutive six (6) months, at least four (4) samples collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. Samples collected under this random sampling program shall be analyzed as specified by FDA. (Refer to Section 6 of this *Ordinance*.)
The bulk milk pickup tanker shall be sampled after the last producer has been picked up and before any additional commingling. These bulk milk pickup tanker samples may be collected ~~from~~ using an approved aseptic sampler. The sample ~~must~~ shall be representative. Bulk milk pickup tanker testing shall be completed prior to processing the milk. ~~Industry plant samplers~~

~~shall be evaluated according to the requirements specified in Section 6. THE EXAMINATION OF MILK AND MILK PRODUCTS and at the frequency addressed in Section 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS of this *Ordinance*. Bulk milk pickup tanker samples found to be positive for drug residues shall be retained as determined necessary by the Regulatory Agency. All presumptive positive test results for drug residues from analysis done on commingled raw milk tanks, bulk milk pickup tankers, farm raw milk tanks (only milk offered for sale) or finished milk or milk product samples must be reported to the Regulatory Agency of the State in which the testing was conducted.~~

All raw milk supplies that have not been transported in bulk milk pickup tankers shall be sampled prior to processing the milk. The sample(s) shall be representative of each farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. Testing of all raw milk supplies that have not been transported in bulk milk pickup tankers shall be completed prior to processing the milk.

NOTE: On-farm producer/processors may freeze a day's raw milk production until they have accumulated enough milk to produce a batch of milk and/or milk product. Each day's raw milk production shall be commingled and tested prior to freezing. If this is the on-farm producer/processor's only raw milk supply, this testing would suffice for the required Appendix N testing for all raw milk supplies that have not been transported in bulk milk pickup tankers, which are required to be completed prior to processing the milk.

All presumptive positive test results for drug residues from analysis conducted on commingled raw milk tanks, bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers, farm raw milk tanks/silos (only milk offered for sale) or finished milk or milk product samples shall be reported to the Regulatory Agency of the State in which the testing was conducted. Bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers samples found to be positive for drug residues, regardless of the drug(s) being tested for or the test(s) being used, shall be retained or disposed of as determined by the Regulatory Agency.

Industry plant samplers shall be evaluated according to the requirements specified in Section 6. THE EXAMINATION OF MILK AND MILK PRODUCTS and at the frequency addressed in Section 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS of this *Ordinance*.

REPORTING AND FARM TRACE BACK:

When a bulk milk pickup tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers is found to be positive for drug residues, regardless of the drug(s) being tested for or the test(s) being used, the Regulatory Agency of the State in which the testing was conducted, shall be immediately notified of the results and the ultimate disposition of the raw milk.

The producer samples from the bulk milk pickup tanker, found to be positive for drug residues, shall be individually tested to determine the farm of origin. The samples shall be tested as directed by the Regulatory Agency.

When a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc, is (are) used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers, is (are) found to be positive (confirmed) for drug residues, the farm of origin of the drug residue has consequently already

been determined and further testing is not required to determine the farm of origin.
Further pickups or use of the violative individual producer's milk shall be immediately discontinued, until such time, that subsequent tests are no longer positive for drug residues.

RECORD REQUIREMENTS:

Results of all testing may be recorded in any format acceptable to the Regulatory Agency that includes at least the following information:

1. Identity of the person doing the test;
2. Identity of the bulk milk pickup tanker or farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. used for the storage of all raw milk supplies that have not been transported in bulk milk pickup tankers being tested*;
3. Date/time the test was performed (Time, Day, Month, and Year);
4. Identity of the test performed/lot #/any and all controls (+/-);
5. Results of the test;
6. Follow-up testing if the initial test was positive/any and all controls (+/-);
7. Site where test was performed, and
8. Prior test documentation shall be provided for a presumptive positive load.

*Include the BTU number(s) of the dairy farms present on the bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers with the above information.

Records of all sample results shall be maintained for a minimum of six (6) months by the industry at the location where the tests were run, and/or another location as directed by the Regulatory Agency.

II. REGULATORY AGENCY RESPONSIBLITIES

Upon receipt of notification from industry of a bulk milk pickup tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers, which contains milk from another State(s), is found to be presumptive positive for drug residues it is the responsibility of the Regulatory Agency of the receiving State to notify the Regulatory Agency(ies) of all States of origin.

MONITORING AND SURVEILLANCE:

Regulatory Agencies shall monitor industry surveillance activities during either routine or unannounced, on-site quarterly inspections to collect samples from bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and to review industry records of ~~the~~ their sampling program. Samples should be collected and analyzed from at least ten percent (10%) of the bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers scheduled to arrive on the day of the inspection. The method used shall be appropriate for the drug being analyzed and shall be capable of detecting the same drugs at the same concentrations as the method being

used by industry. Alternately, the Regulatory Agency or Laboratory Evaluation Officer (LEO) may take known samples with them on the audit visit and observe the industry analyst test the samples. Receiving locations that choose to certify all receiving analysts, certified under the provisions of the NCIMS Laboratory Certification Program, are exempt from the sample collection requirements of this Section. Receiving locations where all approved receiving Industry Analysts and Industry Supervisors successfully participate in a biennial on-site evaluation and annual split sample comparisons by LEOs are also exempt from the sample collection requirements of this Section.

A review shall include, but not be limited to, the following:

1. Is the program an appropriate routine monitoring program for the detection of drug residues?
2. Is the program utilizing appropriate test methods?
3. Is each producer's milk represented in a testing program for drug residues and tested at the frequency prescribed in Section I.-INDUSTRY RESPONSIBILITIES ~~A.~~ of this Appendix for drug residues?
4. Is the program assuring timely notification to the appropriate Regulatory Agency of positive results, the ultimate disposition of the bulk milk pickup tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers~~,~~ and of the trace back to the farm of origin?
5. Is the dairy farm pickup and/or use of the violative individual producer's milk suspended until subsequent testing establishes the milk is no longer positive for drug residues?

To satisfy these requirements:

a. There ~~should~~ shall be an agreement between the Regulatory Agency and industry that ~~would specify~~ specifies how this notification is to take place. This notification ~~must~~ shall be "timely" for example by telephone or fax, and supported in writing.

b. ~~This~~ The ultimate disposition ~~should~~ shall either be prearranged in an agreement between the Regulatory Agency and the industry, or physically supervised by the Regulatory Agency. The milk should be disposed of in accordance with provisions of M-I-06-5 or an FDA and Regulatory Agency reviewed and accepted Beta lactam milk diversion protocol for use as animal feed.

c. All screening test positive (confirmed) loads ~~must~~ shall be broken down (producer trace back) using the same or an equivalent test method (M-I-96-10, latest revision). Confirmation tests (load and producer trace back/permit action) shall be performed by an Official or Officially Designated Laboratory or Certified Industry Supervisor. Positive producers shall be handled in accordance with this Appendix.

d. When a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is (are) used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers, is (are) found to be positive (confirmed) for drug residues, the farm of origin of the drug residue has consequently already been determined and further testing is not required to determine the farm of origin. Confirmation tests shall be performed by an Official or Officially Designated Laboratory or Certified Industry Supervisor. Positive producers shall be handled in accordance with this Appendix.

~~d~~e.The suspension and discontinuance of farm bulk milk tank pick up and/or the use of raw

milk supplies that have not been transported in bulk milk pickup tankers is the responsibility of the industry; under the direction and supervision of the Regulatory Agency. At the discretion of the Regulatory Agency, records ~~should~~ shall be maintained by industry and/or the Regulatory Agency that:

(1) Establish the identity of the producer for raw milk supplies that have not been transported in bulk milk pickup tankers that tested positive or the producer and the identity of the load that tested positive; and

(2) Establish that ~~no~~ milk is not picked up or used from the drug residue positive ~~testing~~ producer until the Regulatory Agency has fulfilled their obligations under Section II-ENFORCEMENT of this Appendix and has cleared the milk for pick up and/or use.

Sufficient records ~~should~~ shall be reviewed to assure that all ~~farm~~ bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers are sampled before additional commingling at the milk receiving facility and the results were made available to the appropriate BTU(s).

The Regulatory Agency shall also perform routine sampling and testing for drug residues determined to be necessary as outlined in Section 6 of this *Ordinance.*

ENFORCEMENT:

If testing reveals milk positive for drug residues, regardless of the drug(s) being tested for or the test(s) being used, the milk shall be disposed of in a manner that removes it from the human or animal food chain, except where acceptably reconditioned under FDA Compliance Policy Guide (CPG 7126.20). The Regulatory Agency shall determine the producer(s) responsible for the violation.

Suspension: Any time milk is found to test as a confirmed positive for a drug residue, the Regulatory Agency shall immediately suspend the producer's Grade "A" permit or equally effective measures shall be taken to prevent the sale of milk containing drug residues.

Penalties: Future ~~pick-ups~~ pickups and/or use of the violative individual producer's milk are prohibited until subsequent testing reveals the milk is free of drug residue. The penalty shall be for the value of all milk on the contaminated load and/or raw milk supply that has not been transported in bulk milk pickup tankers plus any costs associated with the disposition of the contaminated load or raw milk supply that has not been transported in bulk milk pickup tankers. The Regulatory Agency may accept certification from the violative producer's milk marketing cooperative or purchaser of milk as satisfying the penalty requirements.

Reinstatement: The Grade "A" producer's permit may be reinstated, or other action taken, to allow the sale of milk for human food, when a representative sample taken from the producer's milk, prior to commingling with any other milk, is no longer positive for drug residue.

Follow-Up: Whenever a drug residue test is positive, regardless of the drug(s) being tested for or the test(s) being used, an investigation shall be made to determine the cause. The farm inspection is completed by the Regulatory Agency ~~or its agent~~ to determine the cause of the residue and actions taken to prevent future violations including:

1. On-farm changes in procedures necessary to prevent future occurrences as recommended by the Regulatory Agency.
2. Discussion and education on the Drug Residue Avoidance Control measures outlined in Appendix C. of this *Ordinance.*

Permit Revocation: After a third violation in a twelve (12) month period, the Regulatory Agency shall initiate administrative procedures pursuant to the revocation of the producer's Grade "A" permit under the authority of Section 3. Permits of this *Ordinance*, due to repeated violations.

REGULATORY AGENCY RECORDS:

In regards to the industry reporting a positive tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers result, the Regulatory Agency's records ~~should~~ shall indicate the following:

1. What were the Regulatory Agency's directions?
2. When was the Regulatory Agency notified? By whom?
3. What was the identity of the load or farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. when used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers?
4. What screening and/or confirmatory test(s) were used and who were the analyst(s)?
5. What was the disposition of the adulterated milk?
6. Which producer(s) was responsible?
7. Record of negative test results prior to subsequent milk pickup and/or use from the violative producer(s).

III. TESTING PROGRAM FOR DRUG RESIDUES ESTABLISHED

DEFINITIONS:

For purposes of this Appendix the following definitions are to be used:

1. **Presumptive Positive:** A presumptive positive test is a positive result from an initial testing of a bulk milk pickup tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers using an M-a-85 (latest revision) approved test, which has been promptly repeated in duplicate with positive and negative controls that give the proper results using the same test, on the same sample, with one (1) or both of these duplicate retests giving a positive result.
2. **Screening Test Positive (Load or Raw Milk Supply that has Not been Transported in Bulk Milk Pickup Tankers Confirmation):** A screening test positive result is obtained when the presumptive positive sample is tested in duplicate, using the same or equivalent (M-I-96-10, latest revision) test as that used for the presumptive positive, with a positive and negative control that give the proper results, and either or both of the duplicates are positive ~~and the controls give the proper results~~. A screening test positive (load or farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. when used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers confirmation) is to be preformed by an Official State Laboratory, Officially Designated Laboratory or Certified Industry Supervisor using the same or an equivalent test (M-I-96-10, latest revision).
3. **Producer Trace Back/Permit Action:** A producer trace back/permit action test is performed after a screening test positive load is identified by an Official State Laboratory, Officially Designated Laboratory or Certified Industry Supervisor using the same or an

equivalent (M-I-96-10, latest revision) test as was used to obtain the screening test positive (load confirmation). A confirmed producer test positive result is obtained in the same manner as a confirmation (screening test positive) for a load. After an initial positive result (producer presumptive positive) is obtained on a producer sample, that sample is then tested in duplicate using the same test as was used to obtain the producer presumptive positive result. This testing is performed with a positive and negative control and if either or both of the duplicates are positive and the controls give the proper results, the producer sample is confirmed as positive.

NOTE: When a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is used for a milk plant's raw milk supply(ies) that has not been transported in bulk milk pickup tankers, is found to be positive (confirmed) for drug residues, the farm of origin for the drug residue has consequently already been determined and further testing is not required to determine the farm of origin.

4. **Individual Producer Load:** An individual producer bulk milk pickup tanker is a bulk milk pickup tanker, or a compartment(s) of a bulk milk pickup tanker, that contains milk from only one (1) dairy farm.

5. **Individual On-Farm Producer/Processor's Raw Milk Supply:** An individual on-farm producer/processor's raw milk supply may be transported in bulk milk pickup tankers; and/or their raw milk supply may be stored in a farm bulk milk tank(s)/silo(s) on the dairy farm that directly feeds the batch (vat) pasteurizer(s) or constant-level tank of a HTST pasteurization system or piped from the a farm bulk milk tank(s)/silo(s) to a raw milk tank(s) and/or silo(s) in the milk plant that feeds the batch (vat) pasteurizer(s) or constant-level tank of a HTST pasteurization system; and/or other raw milk storage containers.

~~5~~6. **Industry Analyst:** A person under the supervision of ~~the~~ a Certified Industry Supervisor or Industry Supervisor who is assigned to conduct screening of bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers for Appendix N. drug residue requirements.

~~6~~7. **Industry Supervisor/Certified Industry Supervisor:** An individual trained by ~~the~~ a State LEO who is responsible for the supervision and training of Industry Analysts who test milk tank trucks and/or all raw milk supplies that have not been not transported in bulk milk pickup tankers for Appendix N. drug residue requirements.

~~7~~8. **Certified Industry Supervisor:** An Industry Supervisor who is evaluated and listed by a State LEO as certified to conduct drug residue screening tests at industry drug residue screening sites for *Grade "A" PMO,* Appendix N. regulatory actions (confirmation of bulk milk pickup tankers, farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), or other raw milk storage container(s), etc. when used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers, producer trace back and/or permit action).

CERTIFIED INDUSTRY SUPERVISORS; EVALUATION AND RECORDS:
Reference: *EML*

1. **Certified Industry Supervisors/Industry Supervisors/Industry Analysts:** Regulatory Agencies may choose to allow Industry Supervisors to be certified. Under this program, these Certified Industry Supervisors may officially confirm presumptive positive bulk milk pickup

tanker loads and/or all raw milk supplies that have not been transported in bulk milk pickup tankers, and confirm producer milk for regulatory purposes (producer trace back/permit action). In the implementation of Appendix N. of this *Ordinance*, the LEO ~~will~~ shall use the appropriate Appendix N. FDA 2400 Series Form when evaluating Official State Laboratories, Officially Designated Laboratories or Certified Industry Supervisors, Industry Supervisors and Industry Analysts.

The Certified Industry Supervisor/Industry Supervisor shall report to the LEO the ~~result~~ results of all competency evaluations performed on Industry Analysts. The names of all Certified Industry Supervisors, Industry Supervisors and Industry Analysts, as well as their training and evaluation status, shall be maintained by the State LEO and updated as replacement, additions and/or removals occur. The State LEO shall verify (document) that each Certified Industry Supervisor and/or Industry Supervisor has established a program that ensures the proficiency of the Industry Analysts they supervise. The State LEO shall also verify that each Industry Supervisor and Industry Analyst has demonstrated proficiency in performing drug residue analysis at least biennially. Verification may include an analysis of split samples and/or an on-site performance evaluation or another proficiency determination that the State LEO and the FDA Laboratory Proficiency Evaluation Team (LPET) agree is appropriate.

Failure by the Industry Supervisor or Industry Analyst to demonstrate adequate proficiency to the LEO shall lead to their removal from the LEO list of Industry Supervisors and/or Industry Analysts. Reinstatement of their testing status shall only be possible by completing retraining and/or successfully analyzing split samples and/or passing an on-site evaluation or otherwise demonstrating proficiency to the LEO. (Refer to the *EML*, which describes the certification requirements for Certified Industry Supervisors and the training requirements for Industry Supervisors and Industry Analysts.)

2. **Sampling and Testing of Bulk Milk Pickup Tankers:** The bulk milk pickup tanker shall be sampled after the last producer has been picked up and before any additional commingling. The sample ~~must~~ shall be representative. The sample analysis shall be completed before the milk is processed.

3. **Sampling and Testing of Raw Milk Supplies that have Not been Transported in Bulk Milk Pickup Tankers:** All raw milk supplies that have not been transported in bulk milk pickup tankers shall be sampled prior to processing the milk. The sample(s) shall be representative of each farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), or other raw milk storage container(s) supply. Testing of all raw milk supplies that have not been transported in bulk milk pickup tankers shall be completed prior to processing the milk.

~~3~~4. **Bulk Milk Pickup Tanker Unloaded Prior to Negative Test Result:** If the bulk milk pickup tanker is unloaded and commingled prior to obtaining a negative test result and the screening test is positive, the Regulatory Agency shall be immediately notified. The commingled milk is adulterated and unacceptable for human consumption regardless of any subsequent test results from the commingled milk. The milk shall be disposed of under the supervision of the Regulatory Agency.

5. **Raw Milk Supplies that have Not been Transported in Bulk Milk Pickup Tankers Processed Prior to Negative Results:** If the raw milk supply that has not been transported in bulk milk pickup tankers is processed prior to obtaining a negative test result and the screening test is positive, the Regulatory Agency shall be immediately notified. The processed milk is adulterated and unacceptable for human consumption regardless of any subsequent test results from the raw milk supply and/or pasteurized milk or milk products. The processed milk shall be disposed of under the supervision of the Regulatory Agency.

BULK MILK PICKUP TANKER AND/OR ALL RAW MILK SUPPLIES THAT HAVE NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS SCREENING TEST:

1. **Performance Tests/Controls:** Each lot of test kits purchased shall be tested by positive (+) and negative (-) controls, as defined in the SCREENING TESTS NECESSARY TO IMPLEMENT THE PROVISIONS OF APPENDIX N. FOR BULK MILK PICKUP TANKERS AND/OR ALL RAW MILK SUPPLIES THAT HAVE NOT BEEN TRANSPORTED IN RAW BULK MILK PICKUP TANKERS of this Section, in each screening facility prior to its initial use and each testing day thereafter. Records of all positive (+) and negative (-) control performance tests shall be maintained.

2. **Initial Drug Testing Procedures:** The following procedures apply to testing bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers for drug residues following the provisions of Appendix N. Industry analysts may screen bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and receive or reject milk. Milk plants, receiving stations, transfer stations and other screening locations may choose to participate in the Industry Supervisor Certification Program.

a. Industry Presumptive Positive Options: There are two (2) industry options for the milk represented by a presumptive positive sample:

(1) The Regulatory Agency involved (origin and receipt) shall be notified. The appropriate Regulatory Agency shall take control of the presumptive positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers. A written copy of the presumptive positive test results shall follow the initial Regulatory Agency notification. Testing for confirmation of that presumptive positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers shall be in an Official State Laboratory, Officially Designated Laboratory or by a Certified Industry Supervisor at a location acceptable to the Regulatory Agency. Documentation of prior testing shall be provided to the analyst performing the load and/or raw milk supply that has not been transported in bulk milk pickup tankers confirmation. The presumptive positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers may be re-sampled, at the direction of the Regulatory Agency, prior to analysis with the same or equivalent test (M-I-96-10, latest revision), as was used to obtain the presumptive positive result. This analysis shall be done in duplicate with positive (+) and negative (-) controls. If either or both of the duplicate samples are positive and the positive (+) and negative (-) controls give the correct reactions, the sample is deemed a Screening Test Positive (Confirmed Load and/or Raw Milk Supply that has Not been Transported in Bulk Milk Pickup Tankers). A written copy of the test results shall be provided to the Regulatory Agency. The milk, which that sample represents, is no longer available for sale or processing into human food.

(2) The owner of the presumptive positive milk may reject the load and/or raw milk supply that has not been transported in bulk milk pickup tankers without further testing. At that time the milk represented by the presumptive positive test is not available for sale or processing into human food. The milk cannot be re-screened. The Regulatory Agency involved (origin and receipt) shall be notified. Under this option, producer trace backs shall be conducted for the reject load.

NOTE: When a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or

silo(s), other raw milk storage container(s), etc. is used for a milk plant's raw milk supply(ies) that has not been transported in bulk milk pickup tankers, is found to be positive (confirmed) for drug residues, the farm of origin for the drug residue has consequently already been determined and further testing is not required to determine the farm of origin.

3. **Re-Sampling:**

a. Presumptive Results: Occasionally, an error in sampling or a suspicious test result is discovered after a presumptive result is initially obtained. When this happens, the Regulatory Agency may allow the industry to re-sample the bulk milk pickup tanker and/or raw milk supply that has not been transported in bulk milk pickup tankers. The reasons that made the re-sampling necessary shall be clearly documented in testing records and reported to the Regulatory Agency. This written record shall be provided to the Regulatory Agency and shall be maintained with the record of the testing for that load and/or raw milk supply that has not been transported in bulk milk pickup tankers.

b. Screening Test Results: Re-sampling or additional analysis of screening test results should be discouraged. However, the Regulatory Agency may direct re-sampling and/or analysis, when it has determined that procedures for sampling and/or analysis did not adhere to accepted NCIMS practices (*SMEDP,* FDA 2400 Series Forms, Appendix N. and the applicable FDA interpretative or informational memoranda). This decision by the Regulatory Agency ~~must~~ shall be based on objective evidence. A Regulatory Agency allowing re-sampling ~~must~~ shall plan a timely follow-up to identify the problem and initiate corrective action to ensure the problem that led to the need for re-sampling is not repeated. If re-sampling and/or analysis is necessary, it shall include a review of the samplers, analysts, and/or laboratories to identify the problem(s) and initiate corrective action to ensure the problem(s) is not repeated. The reasons that made the re-sampling or analysis necessary shall be clearly documented in testing records maintained by the Regulatory Agency, and shall be maintained with the record of the testing for that load and/or raw milk supply that has not been transported in bulk milk pickup tankers.

4. **Producer Trace Back:** All screening test positive (confirmed) loads ~~must~~ shall be broken down (producer trace back) using the same or an equivalent test method (M-I-96-10, latest revision). Confirmation tests (load and producer trace back/permit action) shall be performed in an Official State Laboratory, or Officially Designated Laboratory or by a Certified Industry Supervisor. Positive producers shall be handled in accordance with this Appendix.

NOTE: When a farm bulk milk tank(s)/silos, milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is used for a milk plant's raw milk supply(ies) that has not been transported in bulk milk pickup tankers, is found to be positive (confirmed) for drug residues, the farm of origin for the drug residue has consequently already been determined and further testing is not required to determine the farm of origin.

Assuring Representative Samples From Individual-Producer Loads And Multiple-Farm Tank Loads From An Individual Producer: Representative samples shall be secured from each farm storage tank(s)/silo(s) of milk prior to loading onto a bulk milk pickup tanker and/or other raw milk supply transportation method at the dairy farm. The representative sample(s) shall travel with the bulk milk pickup tanker and/or other raw milk supply transportation method to a designated location acceptable to the Regulatory Agency.

Record Requirements: Results of all testing may be recorded in any format acceptable to the Regulatory Agency that includes at least the following information:

1. Identity of the person doing the test;
2. Identity of the bulk milk pickup tanker or farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo, or other raw milk storage container(s), etc. used for the storage of raw milk supplies that have not been transported in bulk milk pickup tankers being tested*;
3. Date/time the test was performed (Time, Day, Month and Year);
4. Identity of the test performed/lot #/any and all controls (+/-);
5. Results of the test, if the analysis results are positive the record ~~should~~ shall show:
   a. The identity of each producer contributing to the positive load;
   b. Who at the Regulatory Agency was notified;
   c. When did this notification take place; and
   d. How was this notification accomplished.
6. Follow-up testing if initial test was positive/any and all controls (+/-);
7. Site where test was performed; and
8. Prior test documentation shall be provided for a presumptive positive load.

*Include the BTU number(s) of the dairy farms present on the bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers with the above information.

SCREENING TESTS NECESSARY TO IMPLEMENT THE PROVISIONS OF APPENDIX N. FOR BULK MILK PICKUP TANKERS AND/OR ALL RAW MILK SUPPLIES THAT HAVE NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS:

1. **Performance Tests/Controls (+/-):**
   a. Each lot of kits purchased is tested by positive (+) and negative (-) controls.
   b. Each screening facility runs a positive (+) and negative (-) control performance test each testing day.
   c. All NCIMS Approved Bulk Milk Pickup Tanker and/or All Raw Milk Supplies that have Not been Transported in Bulk Milk Pickup Tankers Screening Tests Include ~~The~~ the Following Format: All presumptive positive test results are to be repeated in duplicate as soon as possible at the direction of the Regulatory Agency on the same sample with single positive (+) and negative (-) controls by a certified analyst (Official State Laboratory, Officially Designated Laboratory or Certified Industry Supervisor) using the same or equivalent test (M-I-96-10, latest revision). If the duplicate tests are negative, with appropriate (+/-) control ~~(+/-)~~ results, ~~are negative (-),~~ the bulk milk pickup tanker and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers is reported as negative. If one (1) or both duplicate test(s) is positive (+), the test result is reported to the Regulatory Agency of the State in which the testing was conducted, as a screening test positive (confirmed).
   d. All positive (+) controls used for drug residue testing kits are labeled to indicate a specific drug and concentration level for that drug.
      (1) For tests that have been validated and only detect Penicillin, Ampicillin, Amoxicillin and Cephapirin, the positive (+) control is Pen G @ 5 ± 0.5 ppb.
      (2) For test kits validated for the detection of Cloxacillin, the positive (+) control may

be Cloxacillin @ 10 ± 1 ppb.

(3) For test kits validated for one (1) drug residue only, the positive (+) control is ± 10% of the safe level/tolerance of the drug residue detected.

2. **Work Area:**
   a. Temperature within specifications of the test kit manufacturer's labeling.
   b. Adequate lighting for conducting the test kit procedure.
3. **Test Kit Thermometers:**
   a. Thermometer traceable to a NIST Certified Thermometer.
   b. Graduation interval not greater than 1°C.
   c. Dial thermometers are not used to determine the temperatures of samples, reagents, refrigerators, or incubators in milk laboratories.
4. **Refrigeration:**
   a. Test kit reagent storage temperature specified by manufacturer.

5. **Balance (Electronic):**
   a. 0.01 g for preparation of positive (+) controls.
   b. Balance with appropriate sensitivity for calibration of pipetting devices within a tolerance of ± 5%. These devices may be calibrated at another location acceptable to the State LEO.
6. **Screening Test Sampling Requirements:**
   a. Temperature of milk in the bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers determined and recorded.
   b. Representative bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers sample for drug residue testing collected.
   c. Samples tested within seventy-two (72) hours of collection.
7. **Screening Test Volumetric Measuring Devices:**
   a. Single use devices provided by kit manufacturers are acceptable for Appendix N. screening analysts.
   b. NCIMS Certified Laboratories require calibrated pipetting/dispensing devices. These devices may be calibrated at another location acceptable to the State LEO.
   c. Measuring devices with tips bearing calibration lines provided by test kit manufacturers are acceptable for Appendix N. screening.

IV. ESTABLISHED TOLERANCES AND/OR SAFE LEVELS OF DRUG RESIDUES

"Safe levels" are used by FDA as guides for prosecutorial discretion. They do not legalize residues found in milk that are below the safe level. In short, FDA uses the "safe levels" as prosecutional guidelines and in full consistency with CNI v. Young stating, in direct and unequivocal language, that the "safe levels" are not binding. They do not dictate any result; they do not limit the Agency's discretion in any way; and they do not protect milk producers, or milk from court enforcement action.

"Safe levels" are not and cannot be transformed into tolerances that are established for animal drugs under Section 512 (b) of the *FFD&CA* as amended. "Safe levels" do not:

1. Bind the courts, the public, including milk producers, or the Agency, including individual FDA employees; and
2. Do not have the "force of law" of tolerances, or of binding rules.

Notification, changes or additions of "safe levels" ~~will~~ shall be transmitted via Memoranda of Information (M-I's).

V. APPROVED METHODS

Regulatory Agencies and industry shall use tests from the most recent revision of M-a-85 for analysis of bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for Beta lactam and/or other particular drug or drug family residues, following the testing procedures specified in Section III of this Appendix. Association of Official Analytical Chemists (AOAC) First Action and AOAC Final Action methods are accepted in accordance with Section 6 of this *Ordinance*. Drug residue detection methods shall be evaluated at the safe level or tolerance. Regulatory action based on each test kit method may be delayed until the evaluation is completed and the method is found to be acceptable to FDA and complies with the provisions of Section 6 of this *Ordinance*.
One (1) year after a drug test(s) ~~have~~ has been evaluated by FDA and accepted by the NCIMS for a particular drug or drug family, other unevaluated drug tests for that particular drug or drug family are not acceptable for screening milk by industry. The acceptance of evaluated drug tests by FDA and the NCIMS for drugs other than Beta lactams does not mandate any additional screening by industry or Regulatory Agencies with the evaluated ~~method~~ test, unless it is determined by the Commissioner of FDA that a potential problem exists with other animal drug residues in the milk supply.

The following text is a mandatory part of this solution but will not be placed in an NCIMS document.

This Proposal also authorizes FDA to make appropriate editorial changes to the NCIMS documents as needed, in accordance with NCIMS *Procedures*, resulting from Proposals that are passed at the 2013 NCIMS Conference, and concurred with by FDA, related to appropriate wording cited in this Proposal addressing drug residue testing and other citations, i.e. will and must changed to shall, as cited throughout this Proposal.

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AND/OR PART II, ITEM 8 OF FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2)

…

Page 94:

Item 5. Sampler (Including Dairy Plant and Industry Plant Samplers at the Receiving Site) **Evaluated Every Two (2) Years and Reports Properly Filed**

a. Samplers shall have their sampling collection procedures evaluated by a certified SSO or a properly delegated Sampling Surveillance Regulatory Official (dSSO) every two (2) years. SSOs or ~~properly delegated Sampling Surveillance Regulatory Officials~~ (dSSOs) are not required to be evaluated for sampling collection procedures.

NOTE: Use *Grade "A"* PMO, Section 5, **ADMINSTRATIVE PROCEDURES**, **INSPECTION FREQUENCY** as a guide: "For the purposes of determining the inspection frequency for bulk milk hauler/samplers, industry plant samplers and dairy plant samplers, the interval shall include the designated twenty-four (24) month period plus the remaining days of the month in which the inspection is due." …

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34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	209
Committee:	Appendix N

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

Specifies that the drug residue testing responsibilities and program requirements outlined in Appendix N apply to those drug residues for which testing is mandated by the Grade "A" PMO (currently the beta-lactams).

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Some drug residue testing is performed for regulatory purposes (i.e., the beta-lactam program, or as mandated by the Commissioner). Drug residue testing outside of that required by Appendix N need not follow the same program requirements.

This proposal does not change current drug residue testing requirements and responsibilities as required by the PMO.

C. Proposed Solution			
Changes to be made on page(s):	23-27; 342-351	of the (X - one of the following):	
X	2011 PMO		2011 EML
	2011 MMSR		2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

SECTION 6. THE EXAMINATION OF MILK AND MILK PRODUCTS

(p 24) Whenever a required drug residue test is confirmed positive, an investigation shall be made to determine the cause, and the cause shall be corrected in accordance with the provisions of Appendix N.

(p 26) The procedures shall be those specified therein for:

1. Standard plate count at 32ºC (agar or Petrifilm method).
2. Alternate methods, for bacterial counts at 32°C (89.6°F), including the Plate Loop Count, Spiral Plate Count and the BactoScan FC for raw milk.
3. Coliform test with solid media or Petrifilm method at 32ºC for all milk and milk products, and the Petrifilm High Sensitivity Coliform Count method for all milk and milk products, except unflavored whole, reduced or low fat and nonfat (skim) milk.
4. A viable bacterial count of nonfat dry milk shall be made in accordance with the procedures in *SMEDP* for the Standard Plate Count of Dry Milk, except agar plates shall be incubated for 72 hours.
5. ~~Beta lactam~~ Required residue screening methods which have been independently evaluated or evaluated by FDA and have been found acceptable by FDA for detecting drug residues in raw milk, or pasteurized milk, or that particular type of pasteurized milk product at current safe or tolerance levels, shall be used for each drug of concern, except those products for which there are not any approved drug test kits available. Regulatory action shall be taken on all confirmed positive results. (Refer to Appendix N.) A result shall be considered positive if it has been obtained by using a method, which has been evaluated and deemed acceptable by FDA and accepted by the NCIMS at levels established in memoranda transmitted periodically by FDA as required by Section IV of Appendix N.

APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE

I. INDUSTRY RESPONSIBILITIES

MONITORING AND SURVEILLANCE:

Industry shall screen all bulk milk pickup tankers, regardless of final use, for ~~Beta-lactam~~ required drug residues (currently beta-lactam). Additionally, other required drug residues shall be screened for by employing a random sampling program on bulk milk pickup tankers when the Commissioner of the FDA determines that a potential problem exists as cited in Section 6. The random bulk milk pickup tanker sampling program shall represent and include, during any consecutive six (6) months, at least four (4) samples collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. Samples collected under this required random sampling program shall be analyzed as specified by FDA. (Refer to Section 6 of this *Ordinance*.)

The bulk milk pickup tanker shall be sampled after the last producer has been picked up and before any additional commingling. These bulk milk pickup tanker samples may be collected from an approved aseptic sampler. The sample must be representative. Bulk milk pickup tanker testing shall be completed prior to processing the milk. Industry plant samplers shall be evaluated according to the requirements specified in Section 6. THE EXAMINATION OF MILK AND MILK PRODUCTS and at the frequency addressed in Section 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS of this *Ordinance*. Bulk milk pickup tanker samples found to be positive for required drug residues shall be retained as determined necessary by the Regulatory Agency. All presumptive positive test results for drug residues from analysis done on commingled raw milk tanks, bulk milk pickup tankers, farm raw milk tanks (only milk offered for sale) or finished milk or milk product samples must be reported to the Regulatory Agency of the State in which the testing was conducted.

REPORTING AND FARM TRACE BACK:

When a bulk milk pickup tanker is found to be positive for drug residues, the Regulatory Agency of the State in which the testing was conducted, shall be immediately notified of the results and the ultimate disposition of the raw milk. The producer samples from the bulk milk pickup tanker, found to be positive for drug residues, shall be individually tested to determine the farm of origin. The samples shall be tested as directed by the Regulatory Agency. Further pickups of the violative individual producer’s milk shall be immediately discontinued, until such time, that subsequent tests are no longer positive for drug residues.

RECORD REQUIREMENTS:

Results of all testing may be recorded in any format acceptable to the Regulatory Agency that includes at least the following information:
1. Identity of the person doing the test;

2. Identity of the bulk milk pickup tanker being tested*;
3. Date/time the test was performed (Time, Day, Month and Year);
4. Identity of the test performed/lot #/any and all controls (+/-);
5. Results of the test;
6. Follow-up testing if initial test was positive/any and all controls (+/-);
7. Site where test was performed, and
8. Prior test documentation shall be provided for a presumptive positive load.

* Include the BTU number(s) of the farms present on the bulk milk pickup tanker with the above information.

Records of all sample results shall be maintained for a minimum of six (6) months by the industry at the location where the tests were run, and/or another location as directed by the Regulatory Agency.

II. REGULATORY AGENCY RESPONSIBILITIES

Upon receipt of notification from industry of a bulk milk pickup tanker, which contains milk from another State(s), is found to be presumptive positive for required drug residues it is the responsibility of the Regulatory Agency of the receiving State to notify the Regulatory Agency(ies) of all States of origin.

MONITORING AND SURVEILLANCE:

Regulatory Agencies shall monitor industry surveillance activities during either routine or unannounced, on-site quarterly inspections to collect samples from bulk milk pickup tankers and to review industry records of the sampling program. Samples should be collected and analyzed from at least ten percent (10%) of the bulk milk pickup tankers scheduled to arrive on the day of the inspection. The method used shall be appropriate for the drug being analyzed and shall be capable of detecting the same drugs at the same concentrations as the method being used by industry. Alternately, the Regulatory Agency or Laboratory Evaluation Officer (LEO) may take known samples with them on the audit visit and observe the industry analyst test the samples. Receiving locations that choose to certify all receiving analysts, certified under the provisions of the NCIMS Laboratory Certification Program, are exempt from the sample collection requirements of this Section. Receiving locations where all approved receiving Industry Analysts and Industry Supervisors successfully participate in a biennial on-site evaluation and annual spilt sample comparisons by LEOs are also exempt from the sample collection requirements of this Section.

A review shall include, but not be limited to, the following:

1. Is the program an appropriate routine monitoring program for the detection of drug residues?
2. Is the program utilizing appropriate test methods?
3. Is each producer's milk represented in a testing program for drug residues and tested at the frequency prescribed in I. A. for drug residues?
4. Is the program assuring timely notification to the appropriate Regulatory Agency of positive results, the ultimate disposition of the bulk milk pickup tanker milk, and of the trace back to the farm of origin?
5. Is the farm pickup suspended until subsequent testing establishes the milk is no longer positive for drug residues?

To satisfy these requirements:
a. There should be an agreement between the Regulatory Agency and industry that would specify how this notification is to take place. This notification must be "timely" for example by telephone or fax, and supported in writing.
b. This ultimate disposition should either be prearranged in an agreement between the Regulatory Agency and the industry, or physically supervised by the Regulatory Agency. The milk should be disposed of in accordance with the provisions of M-I-06-5 or an FDA and Regulatory Agency reviewed and accepted Beta lactam milk diversion protocol for use as animal feed.
c. All screening test positive (confirmed) loads must be broken down (producer trace back) using the same or an equivalent test method (M-I-96-10, latest revision). Confirmation tests (load and producer trace back/permit action) shall be performed by an Official or Officially Designated Laboratory or Certified Industry Supervisor. Positive producers shall be handled in accordance with this Appendix.
d. The suspension and discontinuance of farm bulk milk tank pick up is the responsibility of the industry, under the direction and supervision of the Regulatory Agency. At the discretion of the Regulatory Agency, records should be maintained by industry and/or the Regulatory Agency that:

(1) Establish the identity of the producer and the identity of the load that tested positive; and

(2) Establish that no milk is picked up from the positive testing producer until the Regulatory Agency has fulfilled their obligations under II.-ENFORCEMENT of this Appendix and cleared the milk.

Sufficient records should be reviewed to assure that all farm bulk milk pickup tankers are sampled before commingling and the results were made available to the appropriate BTU(s). The Regulatory Agency shall also perform routine sampling and testing for drug residues determined to be necessary as outlined in Section 6 of this *Ordinance*.

ENFORCEMENT:

If testing reveals milk positive for drug residues, the milk shall be disposed of in a manner that removes it from the human or animal food chain, except where acceptably reconditioned under FDA Compliance Policy Guide (CPG 7126.20). The Regulatory Agency shall determine the producer(s) responsible for the violation.

Suspension: Any time milk is found to test as a confirmed positive for a drug residue through required drug residue testing, the Regulatory Agency shall immediately suspend the producer's Grade "A" permit or equally effective measures shall be taken to prevent the sale of milk containing drug residues.

Penalties: Future pick-ups are prohibited until subsequent testing reveals the milk is free of drug residue. The penalty shall be for the value of all milk on the contaminated load plus any costs associated with the disposition of the contaminated load. The Regulatory Agency may accept certification from the violative producer's milk marketing cooperative or purchaser of milk as satisfying the penalty requirements.
Reinstatement: The Grade "A" producer's permit may be reinstated, or other action taken, to allow the sale of milk for human food, when a representative sample taken from the producer's milk, prior to commingling with any other milk, is no longer positive for drug residue.
Follow-Up: Whenever a drug residue test is positive, an investigation shall be made to determine

the cause. The farm inspection is completed by the Regulatory Agency or its agent to determine the cause of the residue and actions taken to prevent future violations including:

1. On-farm changes in procedures necessary to prevent future occurrences as recommended by the Regulatory Agency.
2. Discussion and education on the Drug Residue Avoidance Control measures outlined in Appendix C. of this *Ordinance.* **Permit Revocation:** After a third violation in a twelve (12) month period, the Regulatory Agency shall initiate administrative procedures pursuant to the revocation of the producer's Grade "A" permit under the authority of Section 3. Permits of this *Ordinance*, due to repeated violations.

REGULATORY AGENCY RECORDS:

In regards to the industry reporting a positive tanker result, the Regulatory Agency's records should indicate the following:

1. What were the Regulatory Agency's directions?
2. When was the Regulatory Agency notified? By whom?
3. What was the identity of the load?
4. What screening and/or confirmatory test(s) were used and who were the analyst(s)?
5. What was the disposition of the adulterated milk?
6. Which producer(s) was responsible?
7. Record of negative test results prior to subsequent milk pickup from the violative producer(s).

III. TESTING PROGRAM FOR DRUG RESIDUES ESTABLISHED
DEFINITIONS:

For purposes of this Appendix the following definitions are to be used:

1. **Presumptive Positive:** A presumptive positive test <u>for a required residue</u> is a positive result from an initial testing of a tanker using an M-a-85 (latest revision) approved test, which has been promptly repeated in duplicate with positive and negative controls using the same test, on the same sample, with one or both of these duplicate retests giving a positive result.
2. **Screening Test Positive (Load Confirmation):** A screening test positive result is obtained when the presumptive positive sample is tested in duplicate, using the same or equivalent (M-I96-10, latest revision) test as that used for the presumptive positive, with a positive and negative control, and either or both of the duplicates are positive and the controls give the proper results. A screening test positive (load confirmation) is to be ~~preformed~~ <u>performed</u> by an Official State Laboratory, Officially Designated Laboratory or Certified Industry Supervisor using the same or an equivalent test (M-I-96-10, latest revision).
3. **Producer Trace Back/Permit Action:** A producer trace back/permit action test is performed after a screening test positive load is identified by an Official State Laboratory, Officially Designated Laboratory or Certified Industry Supervisor using the same or an equivalent (M-I-9610, latest revision) test as was used to obtain the screening test positive (load confirmation). A confirmed producer test positive result is obtained in the same manner as a confirmation (screening test positive) for a load. After an initial positive result (producer presumptive positive) is obtained on a producer sample, that sample is then tested in duplicate using the same test as was used to obtain the producer presumptive positive result. This testing is performed with a positive and negative control and if either or both of the duplicates are positive and the controls give the proper results, the producer sample is confirmed as positive.
4. **Individual Producer Load:** An individual producer bulk milk pickup tanker is a tanker, or a

compartment of a tanker, that contains milk from only one (1) dairy farm.

5. **Industry Analyst:** A person under the supervision of the Certified Industry Supervisor or Industry Supervisor who is assigned to conduct screening of bulk milk pickup tankers for Appendix N. drug residue requirements.
6. **Industry Supervisor/Certified Industry Supervisor:** An individual trained by the State LEO who is responsible for the supervision and training of Industry Analysts who test milk tank trucks for Appendix N. drug residue requirements.
7. **Certified Industry Supervisor:** An Industry Supervisor who is evaluated and listed by a State LEO as certified to conduct drug residue screening tests at industry drug residue screening sites for *Grade "A" PMO*, Appendix N. regulatory actions (confirmation of tankers, producer trace back and/or permit actions).

CERTIFIED INDUSTRY SUPERVISORS; EVALUATION AND RECORDS:
Reference: *EML*

1. **Certified Industry Supervisors/Industry Supervisors/Industry Analysts:** Regulatory Agencies may choose to allow Industry Supervisors to be certified. Under this program, these Certified Industry Supervisors may officially confirm presumptive positive tanker loads and confirm producer milk for regulatory purposes (producer trace back/permit action). In the implementation of Appendix N. of this *Ordinance*, the LEO will use the appropriate Appendix N. FDA 2400 Series Form when evaluating Official State Laboratories, Officially Designated Laboratories or Certified Industry Supervisors, Industry Supervisors and Industry Analysts. The Certified Industry Supervisor/Industry Supervisor shall report to the LEO the result of all competency evaluations performed on Industry Analysts. The names of all Certified Industry Supervisors, Industry Supervisors and Industry Analysts, as well as their training and evaluation status, shall be maintained by the State LEO and updated as replacement, additions and/or removals occur. The State LEO shall verify (document) that each Certified Industry Supervisor and/or Industry Supervisor has established a program that ensures the proficiency of the Industry Analysts they supervise. The State LEO shall also verify that each Industry Supervisor and Industry Analyst has demonstrated proficiency in performing drug residue analysis at least biennially. Verification may include an analysis of split samples and/or an on-site performance evaluation or another proficiency determination that the State LEO and the Laboratory Proficiency Evaluation Team (LPET) agree is appropriate. Failure by the Industry Supervisor or Industry Analyst to demonstrate adequate proficiency to the LEO shall lead to their removal from the LEO list of Industry Supervisors and/or Industry Analysts. Reinstatement of their testing status shall only be possible by completing retraining and/or successfully analyzing split samples and/or passing an on-site evaluation or otherwise demonstrating proficiency to the LEO. (Refer to the *EML*, which describes the certification requirements for Certified Industry Supervisors and the training requirements for Industry Supervisors and Industry Analysts.)

1. **Sampling and Testing of Bulk Milk Pickup Tankers:** The bulk milk pickup tanker shall be sampled after the last producer has been picked up and before any additional commingling. The sample must be representative. The sample analysis shall be completed before the milk is processed.
2. **Tanker Unloaded Prior to Negative Test Result:** If the bulk milk pickup tanker is unloaded and commingled prior to obtaining a negative test result and the screening test is positive, the Regulatory Agency shall be immediately notified. The commingled milk is adulterated and unacceptable for human consumption regardless of any subsequent test results from the

commingled milk. The milk shall be disposed of under the supervision of the Regulatory Agency.

BULK MILK PICKUP TANKER SCREENING TEST:

1. **Performance Tests/Controls:** Each lot of test kits purchased shall be tested by positive (+) and negative (-) controls, as defined in the SCREENING TESTS NECESSARY TO IMPLEMENT THE PROVISIONS OF APPENDIX N. FOR BULK MILK PICKUP TANKERS of this Section, in each screening facility prior to its initial use and each testing day thereafter. Records of all positive (+) and negative (-) control performance tests shall be maintained.
2. **Initial Drug Testing Procedures:** The following procedures apply to testing bulk milk pickup tankers for <u>required</u> drug residues following the provisions of Appendix N. Industry analysts ~~may~~ <u>must</u> screen tankers and receive or reject milk. Milk plants, receiving stations, transfer stations and other screening locations may choose to participate in the Industry Supervisor Certification Program.

   a. Industry Presumptive Positive Options: There are two (2) industry options for the milk represented by a <u>required drug residue</u> presumptive positive sample:

      (1) The Regulatory Agency involved (origin and receipt) shall be notified. The appropriate Regulatory Agency shall take control of the presumptive positive load. A written copy of the presumptive positive test results shall follow the initial Regulatory Agency notification. Testing for confirmation of that presumptive positive load shall be in an Official State Laboratory, Officially Designated Laboratory or by a Certified Industry Supervisor at a location acceptable to the Regulatory Agency. Documentation of prior testing shall be provided to the analyst performing the load confirmation. The presumptive positive load may be re-sampled, at the direction of the Regulatory Agency, prior to analysis with the same or equivalent test (M-I-96-10, latest revision), as was used to obtain the presumptive positive result. This analysis shall be done in duplicate with positive (+) and negative (-) controls. If either or both of the duplicate samples are positive and the positive (+) and negative (-) controls give the correct reactions, the sample is deemed a Screening Test Positive (Confirmed Load). A written copy of the test results shall be provided to the Regulatory Agency. The milk, which that sample represents, is no longer available for sale or processing into human food.

      (2) The owner of the presumptive positive milk may reject the load without further testing. At that time the milk represented by the presumptive positive test is not available for sale or processing into human food. The milk cannot be re-screened. The Regulatory Agency involved (origin and receipt) shall be notified. Under this option, producer trace backs shall be conducted.

3. **Re-Sampling:**

a. Presumptive Results: Occasionally, an error in sampling or a suspicious test result is discovered after a presumptive result is initially obtained. When this happens, the Regulatory Agency may allow the industry to re-sample the bulk milk pickup tanker. The reasons that made the re-sampling necessary shall be clearly documented in testing records and reported to the Regulatory Agency. This written record shall be provided to the Regulatory Agency and shall be maintained with the record of the testing for that load.

b. Screening Test Results: Re-sampling or additional analysis of screening test results should be discouraged. However, the Regulatory Agency may direct re-sampling and/or analysis, when it has

determined that procedures for sampling and/or analysis did not adhere to accepted NCIMS practices (*SMEDP*, FDA 2400 Series Forms, Appendix N. and the applicable FDA interpretative or informational memoranda). This decision by the Regulatory Agency must be based on objective evidence. A Regulatory Agency allowing re-sampling must plan a timely follow-up to identify the problem and initiate corrective action to ensure the problem that led to the need for re-sampling is not repeated. If re-sampling and/or analysis is necessary, it shall include a review of the samplers, analysts, and/or laboratories to identify the problem(s) and initiate corrective action to ensure the problem(s) is not repeated. The reasons that made the re-sampling or analysis necessary shall be clearly documented in testing records maintained by the Regulatory Agency, and shall be maintained with the record of the testing for that load.

4. **Producer Trace Back:** All screening test positive (confirmed) loads must be broken down (producer trace back) using the same or an equivalent test method (M-I-96-10, latest revision). Confirmation tests (load and producer trace back/permit action) shall be performed in an Official State Laboratory, or Officially Designated Laboratory or by a Certified Industry Supervisor. Positive producers shall be handled in accordance with this Appendix.

Assuring Representative Samples From Individual-Producer Loads And Multiple-Farm Tank Loads From An Individual Producer: Representative samples shall be secured from each farm storage tank(s) of milk prior to loading onto a bulk milk pickup tanker at the dairy farm. The representative sample(s) shall travel with the bulk milk pickup tanker to a designated location acceptable to the Regulatory Agency.

Record Requirements: Results of all testing may be recorded in any format acceptable to the Regulatory Agency that includes at least the following information:
1. Identity of the person doing the test; 2. Identity of the bulk milk pickup tanker being tested*;
3. Date/time the test was performed (Time, Day, Month and Year);
4. Identity of the test performed/lot #/any and all controls (+/-);
5. Results of the test, if the analysis results are positive the record should show:

a. The identity of each producer contributing to the positive load;
b. Who at the Regulatory Agency was notified;
c. When did this notification take place; and
d. How was this notification accomplished.

1. Follow-up testing if initial test was positive/any and all controls (+/-);
2. Site where test was performed; and
3. Prior test documentation shall be provided for a presumptive positive load.

* Include the BTU number(s) of the farms present on the bulk milk pickup tanker with the above information.

SCREENING TESTS NECESSARY TO IMPLEMENT THE PROVISIONS OF APPENDIX N. FOR BULK MILK PICKUP TANKERS:

1. **Performance Tests/Controls (+/-):**
a. Each lot of kits purchased is tested by positive (+) and negative (-) controls.
b. Each screening facility runs a positive (+) and negative (-) control performance test each testing day.

c. All NCIMS Approved Bulk Milk Pickup Tanker Screening Tests Include The Following Format: All presumptive positive test results are to be repeated in duplicate as soon as possible at the direction of the Regulatory Agency on the same sample with single positive (+) and negative (-) controls by a certified analyst (Official State Laboratory, Officially Designated Laboratory or Certified Industry Supervisor) using the same or equivalent test (M-I-96-10, latest revision). If the duplicate tests, with appropriate control (+/-) results are negative (-), the tanker is reported as negative. If one or both duplicate test(s) is positive (+), the test result is reported to the Regulatory Agency of the State in which the testing was conducted, as a screening positive.
d. All positive (+) controls used for drug residue testing kits are labeled to indicate a specific drug and concentration level for that drug.
(1) For tests that only detect Penicillin, Ampicillin, Amoxicillin and Cephapirin, the positive (+) control is Pen G @ 5 ± 0.5 ppb.
(2) For test kits validated for the detection of Cloxacillin, the positive (+) control may be Cloxacillin @ 10 ± 1 ppb.
(3) For test kits validated for one (1) drug residue only, the positive (+) control is ± 10% of the safe level/tolerance of the drug residue detected.

2. **Work Area:**
a. Temperature within specifications of the test kit manufacturer's labeling.
b. Adequate lighting for test kit procedure.

3. **Test Kit Thermometers:**
a. Thermometer traceable to a NIST Certified Thermometer.
b. Graduation interval not greater than 1°C.
c. Dial thermometers are not used to determine temperatures of samples, reagents, refrigerators, or incubators in milk laboratories.

4. **Refrigeration:**
a. Test kit reagent storage temperature specified by manufacturer.

5. **Balance (Electronic):**
a. 0.01 g for preparation of positive (+) controls.
b. Balance with appropriate sensitivity for calibration of pipetting devices within a tolerance of ± 5%. These devices may be calibrated at another location acceptable to the State LEO.

6. **Screening Test Sampling Requirements:**
a. Temperature of milk in the bulk milk pickup tanker determined and recorded.
b. Representative bulk milk pickup tanker sample for drug residue testing collected.
c. Samples tested within seventy-two (72) hours of collection.

7. **Screening Test Volumetric Measuring Devices:**
a. Single use devices provided by kit manufacturers are acceptable for Appendix N. screening analysts.
b. NCIMS Certified Laboratories require calibrated pipetting/dispensing devices. These devices may be calibrated at another location acceptable to the State LEO.
c. Measuring devices with tips bearing calibration lines provided by test kit manufacturers are acceptable for Appendix N. screening.

IV. ESTABLISHED TOLERANCES AND/OR SAFE LEVELS OF DRUG RESIDUES

"Safe levels" are used by FDA as guides for prosecutorial discretion. They do not legalize residues found in milk that are below the safe level. In short, FDA uses the "safe levels" as prosecutional guidelines and in full consistency with CNI v. Young stating, in direct and unequivocal language, that the "safe levels" are not binding. They do not dictate any result; they do not limit the Agency's discretion in any way; and they do not protect milk producers, or milk from court enforcement action. "Safe levels" are not and cannot be transformed into tolerances that are established for animal drugs under Section 512 (b) of the *FFD&CA* as amended . "Safe levels" do not:

1. Bind the courts, the public, including milk producers, or the Agency, including individual FDA employees; and
2. Do not have the "force of law" of tolerances, or of binding rules. Notification, changes or additions of "safe levels" will be transmitted via Memoranda of Information (M-I's).

V. APPROVED METHODS

Regulatory Agencies and industry shall use tests from the most recent revision of M-a-85 for required analysis of bulk milk pickup tankers, currently for Beta lactam residues, following the testing procedures specified in Section III of this Appendix. Association of Official Analytical Chemists (AOAC) First Action and AOAC Final Action methods are accepted in accordance with Section 6 of this *Ordinance*. Drug residue detection methods shall be evaluated at the safe level or tolerance. Regulatory action based on each test kit method may be delayed until the evaluation is completed and the method is found to be acceptable to FDA and complies with the provisions of Section 6 of this *Ordinance*. One (1) year after test(s) have been evaluated by FDA and accepted by the NCIMS for a particular required drug or required drug family, other unevaluated tests are not acceptable for screening milk for required drug residue testing. The acceptance of evaluated tests for non-required drug residues does not mandate any additional screening by industry with the evaluated method.

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34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	210
Committee:	Appendix N

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This Proposal updates criterion for the Commissioner of FDA to utilize for determination that a potential problem exists with animal drug residues or other contaminants in the milk supply that would result in additional analysis for the contaminant by a method(s) determined by FDA to be effective in determining compliance with actionable levels or established tolerances.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE provides the basis for antibiotic residue screening requirements within the PMO. The required screening of Beta lactam drug residues has been successful in reducing the already low incidence of 0.021%[1], a decrease of 72% in the past 12 years[2,3]. At the request of NCIMS, FDA is currently undertaking a risk analysis of APPENDIX N to determine if any change in the residue testing program is warranted.

The PMO also provides the Commissioner of FDA authority to require additional testing if a potential problem exists with animal drug residues. A determination of the Commissioner of FDA is based upon five redundant criterion. This proposal streamlines the Commissioner of FDA authority.

[1] GLH Incorporated. February 13, 2012. National Milk Drug Residue Database Fiscal Year 2011 Annual Report.
[2] *Ibid.*
[3] GLH Incorporated. January 31, 2001. National Milk Drug Residue Database Fiscal Year 2001 Annual Report

C. Proposed Solution

Changes to be made on page(s): 25 of the (X - one of the following):

X	2011 PMO		2011 EML
	2011 MMSR		2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

Make the following change to the 2011 PMO.

~~Strike out~~ text to be deleted and underlined text to be added.

SECTION 6. THE EXAMINATION OF MILK AND MILK PRODUCTS

Page 25

Examinations and tests to detect adulterants, including pesticides, shall be conducted, as the Regulatory Agency requires. When the Commissioner of the FDA determines that a potential problem exists with animal drug residues or other contaminants in the milk supply, samples shall be analyzed for the contaminant by a method(s) determined by FDA to be effective in determining compliance with actionable levels or established tolerances. This testing will continue until such time that the Commissioner of the FDA is reasonably assured that the problem has been corrected. The determination of a problem is to be based on current and relevant scientific information and with consultation of the NCIMS Board of Directors. ~~The determination of a problem is to be based upon:~~

~~1. Sample survey results;~~
~~2. USDA tissue residue data from cull and veal dairy animals;~~
~~3. Animal drug disappearance and sales data;~~
~~4. State feed back; and~~
~~5. Other relevant information.~~

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34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	211
Committee:	Lab & 2400

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

Change the conversion of 40°F to be 4.5°C instead of 4.4°C in the PMO and on the 2400 series forms.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Laboratories are required to have thermometers that have a graduation/recording interval of 0.5°C increments. With liquid-in-glass technology interpolating to 4.4°C was possible. With the new digital technology, if a thermometer is graduated in 0.5°C increments, it is not possible to interpolate to 4.4°C.

The difference in actual temperature is insignificant. When calculating the conversion 4.4°C truly equals 39.9°F and 4.5°C equals 40.1°F.

There is no public health significance.

C. Proposed Solution

Changes to be made on page(s): 29, 132, 133, 136, 151, 219 & 356 of the (X - one of the following):

X	2011 PMO		2011 EML
	2011 MMSR	X	2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

Modify the 2011PMO in the following places:

Page 29 Section 7 Standards for Grade "A" Milk and Milk Products; Table I Chemical, Physical , Bacteriological and Temperature Standards

GRADE "A" RAW MILK AND MILK PRODUCTS FOR PASTEURIZATION, ULTRA-PASTEURIZATION OR ASEPTIC PROCESSING AND PACKGING
NOTE: Milk sample submitted for testing cooled and maintained at 0ºC (32ºF) to ~~4.4~~ 4.5ºC (40ºF), where sample temperature is >~~4.4~~ 4.5ºC (40ºF), but ≤7.0ºC (45°F) and less than three (3) hours after collection has not increased in temperature.

and

GRADE "A" PASTEURIZED MILK AND MILK PRODUCTS
NOTE: Milk sample submitted for testing cooled and maintained at 0ºC (32ºF) to ~~4.4~~ 4.5ºC (40ºF), where sample temperature is >~~4.4~~ 4.5ºC (40ºF), but ≤7.0ºC (45ₒF) and less than three (3) hours after collection has not increased in temperature.

Page 132 Appendix B. Milk Sampling, Hauling and Transportation; Item I Milk Sampling and Hauling Procedures

EVALUATION OF BULK MILK HAULER/SAMPLER PROCEDURES:
2. **Equipment Requirements:**
a. Sample rack and compartment to hold all samples collected.
b. Refrigerant to hold temperature of milk samples between 0ºC- ~~4.4~~ 4.5ºC (32ºF- 40°F).

Page 133 Appendix B. Milk Sampling, Hauling and Transportation; Item I Milk Sampling and Hauling Procedures

EVALUATION OF BULK MILK HAULER/SAMPLER PROCEDURES:
7. **Sampling Responsibilities:**
a. All sample containers and single-service sampling tubes used for sampling shall comply with all the requirements that are in the current edition of *SMEDP*. Samples shall be cooled to and held between 0°C (32°F) and ~~4.4~~ 4.5°C (40°F) during transit to the laboratory.

Page 136 Appendix B. Milk Sampling, Hauling and Transportation; Item V Milk Tank Truck Permitting and Inspection

MILK TANK AND TRUCK STANDARDS:
1. **Samples and Sampling Equipment:** (When provided)
g. Samples are maintained at an acceptable temperature 0ºC-~~4.4~~ 4.5ºC (32ºF-40ºF) and a temperature control sample is provided.

Page 151 Appendix C. Dairy Farm Construction Standards; Item IV Guidelines for conventional stall barn with Gutter Grates over Liquid Manure Storage

For Example: (Second Paragraph)

Total cold weather capacity of twenty (20) air changes per hour equals five (5) times the minimum capacity: 3,264 x 5 = 16,320 cfm. Use two (2) fans of 3,264 each and two (2) fans of 4,896 cfm each to make up the total. Build two (2) fan houses. Mount one 3,264 cfm and one 4,896 cfm fan in each. Operate one 3,264 cfm fan continuously. Thermostatically control the second 3,264 cfm fan at ~~4.4~~ 4.5ºC (40°F).

Page 219 Appendix H Pasteurization Equipment and Procedures and Other Equipment; Item I HTST Pasteurization - Operation of HTST Systems

9. The warm milk or milk product passes through the cooling section, where coolant, on the sides of thin stainless steel surfaces opposite the pasteurized milk or milk product, reduces its temperature to ~~4.4~~ 4.5°C (40°F) and below.

Page 356 Appendix O Vitamin Fortification of Fluid Milk Products

PROBLEMS INVOLVED WITH FORTIFICATION (Fourth Paragraph)
Vitamin A and D fortified skim milk products are subject to decreases in vitamin A, because the vitamin is no longer protected by fat as it is in whole milk. In fluid skim or low fat milk, added vitamin A deteriorates gradually during normal storage of the milk at ~~4.4~~ 4.5°C (40°F) in the dark but is destroyed rapidly when the milk is exposed to sunlight in transparent glass bottles or translucent plastic containers.

And several 2400 series forms that refer to sample storage temperature or refrigerator temperature as 0.0 - 4.4°C.

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34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	212
Committee:	MMSR

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This Proposal provides clarifications to the MMSR related to the utilization of a laboratory that is not IMS Listed or using a laboratory procedure(s) that an IMS Listed laboratory is not approved for. It also clarifies that when phosphatase and/or drug residue testing are required on a specific milk and/or milk product and the specific test(s) is not conducted in the preceding six (6) months of a rating or check rating that the milk plant shall be debited and shall lose points off of the Sanitation Compliance Rating.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Provides clarification to the existing wording in the MMSR related to the required action of withdrawing the IMS Listing of a BTU or milk plant when it is determined that the Regulatory Agency has or is utilizing a laboratory that is not IMS Listed or an IMS Listed laboratory using a laboratory procedure(s) that the laboratory is not approved for.

Also, provides clarification that when phosphatase and/or drug residue testing are required on a specific milk and/or milk product and the test(s) is not conducted in the preceding six (6) months of a rating or check rating that the milk plant shall be debited and shall lose points off of the Sanitation Compliance Rating. For the lack of milk plant required drug residue testing that will be similar to how that violation/debit (Bacterial Count or Drug Residue Analysis*) is currently being handled for dairy farms included in a BTU listing as cited on FORM FDA 2359k-Status of Raw Milk for Pasteurization. For the lack of milk plant required phosphatase testing that violation/debit will be included with the current coliform violation/debit (Coliform Count*) as cited on FORM FDA 2359L-Status of Milk Plants.

C. Proposed Solution			
Changes to be made on page(s):	6,7,10,11,15,16,37,63 & 64	of the (X - one of the following):	
	2011 PMO		2011 EML
X	2011 MMSR		2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

MAKE THE FOLLOWING CHANGES TO THE 2011 MMSR:

~~Strike through~~ text to be deleted and <u>underline</u> text to be added.

B. RATING METHODS FOR RAW MILK FOR PASTEURIZATION …

2. COLLECTION OF DATA …

Page 6:

d. Recording of Inspection Data …

2.) Sanitary conditions are evaluated in terms of the requirements of Section 7 of the *Grade "A" PMO*. Professional judgment alone shall dictate whether an observed deficiency is representative of significant day-to-day sanitary conditions or is an anomaly. When significant violations of any given requirement are noted, the corresponding Item(s) or sub-item(s) on the individual FORM FDA 2359a-DAIRY FARM INSPECTION REPORT are marked with an "X". Each sub-item found in violation ~~should~~ <u>shall</u> be carefully marked, as this affects the computation of the Sanitation Compliance Rating. …

Page 7:

e. Recording of Laboratory and Other Test Data

1.) Regulatory Agency records are used in determining compliance with bacterial, drug residue, somatic cell, and cooling temperature requirements. The acceptance of data from official or officially designated laboratories is contingent upon the utilization of standard procedures by the laboratories concerned. Accordingly, it is necessary for the SRO to determine from the official State Laboratory Certifying Agency that both sampling and laboratory procedures have been approved in accordance with the methods of the current edition of the *Evaluation of Milk Laboratories* (*EML*). Ratings shall not be conducted when an approved laboratory is not utilized by the Regulatory Agency for the necessary tests. <u>The utilization of a laboratory that is not IMS Listed or an IMS Listed laboratory that is utilizing a laboratory procedure for which they are not approved for the testing of *Grade "A" PMO* required samples for official regulatory</u>

purposes, shall warrant an immediate withdrawal of the shipper from the *IMS List*.

2.) Compliance with bacterial, drug residue, somatic cell, and cooling temperature requirements is based on whether, at the time of the rating, a dairy farm meets the standards of Section 7 of the *Grade "A" PMO*. Credit for bacterial, somatic cell and cooling temperature requirements shall be given if no more than two (2) of the last four (4) sample results exceed the limits. Provided, that the last sample result is within the limit. ~~No credit~~ Credit for compliance with bacterial, drug residue, somatic cell and cooling temperature requirements shall not be given when less than the required number of samples have been examined during the preceding six (6) months. For rating purposes, the preceding six (6) months is considered to be the elapsed period of the month in which the rating is made and the preceding six (6) months. Dairy farms, which have had a permit for less than six (6) months at the time of the rating and for which the Regulatory Agency has not yet examined the required number of samples, shall be given credit. Provided, that the last sample result is within the limits.

3.) The SRO may utilize the Regulatory Agency's records in determining compliance with those Items of sanitation which require laboratory tests to complete the evaluation.

…

C. RATING METHODS FOR MILK PLANTS, RECEIVING STATION AND TRANSFER STATIONS …

Page 10:

2. COLLECTION OF DATA

Data from which ratings are determined are obtained by SROs from the records on file with the Regulatory Agency and from the evaluation of sanitary practices and facilities at the milk plants, receiving stations and/or transfer stations. Receiving stations and transfer stations may be considered as an integral part of the milk plant to which milk is shipped. Therefore, all such receiving and/or transfer stations not having individual ratings and supplying milk to the milk plant selected for the rating shall be included. Receiving stations and/or transfer stations, which are not an integral part of a milk plant, shall have individual ratings and may be rated separate from their BTUs.

a. Recording of Inspection Data …

2.) Sanitary conditions are evaluated in terms of the requirements of Section 7 of the *Grade "A" PMO.* Professional judgment alone shall dictate whether an observed deficiency is representative of significant day-to-day sanitary conditions or is an anomaly. When significant violations of any given requirement are noted, the corresponding Item(s) or sub-item(s) on the individual FORM FDA 2359-MILK PLANT INSPECTION REPORT are marked with an "X". Each sub-item found in violation ~~should~~ shall be carefully marked, as this affects the computation of the Sanitation Compliance Rating.

3.) The average number of pounds of milk and/or milk products processed daily is needed for computing the rating and is entered in the appropriate place at the top of FORM FDA 2359-MILK PLANT INSPECTION REPORT. When a deficiency in a milk plant affects only one (1) type of packaging, i.e., paper, glass, single-service

plastics, multi-use plastics, dispenser, cottage cheese, sour cream or yogurt containers; or the capping of these containers; or an individual pasteurization unit used, i.e., vat, HTST or HHST; or product(s) that ~~have~~ has not been pasteurized at the minimum pasteurization times and temperatures; only the quantity of all milk and/or milk products affected by the deficiency, rather than the entire milk plant's production, is recorded for use in the computation of the milk plant's Sanitation Compliance Rating. Only violations of Items 16p, 18p and 19p of the *Grade "A" PMO* are to receive partial debits. Provided, that bacterial count, coliform count, phosphatase, drug residue and cooling temperature may be partially debited for the particular milk and/or milk product involved. All other violations ~~should~~ shall be considered as affecting the entire production of the milk plant.

Page 11:

b. Recording of Laboratory and Other Test Data

1.) Regulatory Agency records are used in determining compliance with bacterial, coliform, phosphatase, drug residue, and cooling temperature requirements. The acceptance of data from official or officially designated laboratories is contingent upon the utilization of standard procedures by the laboratories concerned. Accordingly, it is necessary for the SRO to determine from the official State Laboratory Certifying Agency that both sampling and laboratory procedures have been approved in accordance with the methods of the current edition of the *EML*. Ratings and HACCP listing audits shall not be conducted when an approved laboratory has not been utilized by the Regulatory Agency for the necessary tests. The utilization of a laboratory that is not IMS Listed or an IMS Listed laboratory that is utilizing a laboratory procedure for which they are not approved for the testing of *Grade "A" PMO* required samples for official regulatory purposes, shall warrant an immediate withdrawal of the shipper from the *IMS List*.

2.) Compliance with bacterial, coliform, phosphatase, drug residue, and cooling temperature requirements is based on whether, at the time of the rating, a milk plant's Grade "A" milk and/or milk products meet the standards of Section 7 of the *Grade "A" PMO*. Each milk and/or milk product, including commingled raw milk prior to pasteurization, for each of the above applicable requirements, shall be debited if two (2) of the last four (4) sample results exceed the limit(s), and the last sample result is in violation. A debit shall be given when less than the required number of samples has been examined during the preceding six (6) months. For rating purposes, the preceding six (6) months is considered to be the elapsed period for the month in which the rating is made and the preceding six (6) months. Milk plants which have had a permit for less than six (6) months at the time of the rating or which do not operate on a year round basis and for which the Regulatory Agency has not yet examined the required number of samples shall not be debited. Provided, that the last sample result is within the limit(s).

3.) The SRO may utilize Regulatory Agency's records in determining compliance with those Items of sanitation, which require laboratory tests to complete the evaluation. Official records of Equipment Tests may also be used in lieu of performing such Equipment Tests during the rating. Provided, that the SRO is satisfied as to the competency of the Regulatory Agency's personnel to perform these Equipment Tests

as described in Appendix I. of the *Grade "A" PMO*. …

Page 15:

3. COMPUTATION OF SANITATION COMPLIANCE RATING …

For Example: 86,340 pounds processed per day will result in an entry of 863 in the "Pounds Processed Daily (100# Units)" column.

If the milk plant's daily output varies, the recorded quantity is the daily average, based on actual operating days, for the week preceding the rating. Violations of Items or sub-items are indicated by an "X" or by inserting the point value of the violation in the appropriate column(s). When a deficiency in a milk plant affects one (1) type of packaging, capping, or individual pasteurization unit used, the number of pounds of all milk and/or milk products so packaged, capped or pasteurized are debited. In such cases, entries are made on separate lines below the name of the milk plant. The name or names of the milk and/or milk product(s) affected by the violation(s) of Items 16p, 18p, 19p, or bacterial, coliform, phosphatase, drug residue or cooling temperature standards of the *Grade "A" PMO* is entered in the "Name of Plant" column, together with a parenthetic entry of the total volume in 100 pound units (cwt.) of the milk and/or milk product(s) involved. Care shall be taken not to enter this quantity in the "Pounds Processed Daily (100# Units)" column where it would again be included in the total pounds processed daily. (Refer to Section H, #s 14 and 15 for examples.) …

Page 16:

d. The computation procedure for a milk plant is similar to that for dairy farms, except that a modified procedure is necessary in computing debits for violations involving only one (1) type of packaging, capping or individual pasteurization unit used; or individual product(s) violating the bacterial, coliform, phosphatase, drug residue, or cooling temperature standards; and for violations involving receiving and/or transfer stations. The latter is explained in the preceding paragraph. For such violations, the entry in the "Total Debits" column is multiplied by the actual number of pounds of milk and/or milk product involved, as entered parenthetically in the "Name of Plant" column, rather than by the milk plant's entire production from the "Pounds Processed Daily (100# Units)" column. This figure is entered in the "Pounds Processed Daily (100# Units) X Total Debits" column. …

G. **EXAMPLES OF RATING, NCIMS HACCP LISTING, AND ASEPTIC PROCESSING AND PACKAGING PROGRAM LISTING FORMS** …

Page 37:

FORM FDA 2359L-STATUS OF MILK PLANTS

Bacteria Count~~*~~ or Drug Residue Analysis*
Coliform Count~~*~~ or Phosphatase Analysis*

FORM FDA 2359L (10/~~11~~13)

H. **EXAMPLES OF HOW TO PROPERLY COMPLETE RATING, NCIMS HACCP LISTING, AND ASEPTIC PROCESSING AND PACKAGING PROGRAM LISTING FORMS** …

Pages 63 and 64:

FORM FDA 2359L-STATUS OF MILK PLANTS

Bacteria Count~~*~~ or Drug Residue Analysis*
Coliform Count~~*~~ or Phosphatase Analysis*

FORM FDA 2359L (10/~~11~~13)

NOTE: *This Proposal shall take immediate effect upon the issuance of the IMS-a, Actions from the 2013 National Conference on Interstate Milk Shipments, following FDA's concurrence with the NCIMS Executive Board.*

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34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	213
Committee:	MMSR

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This Proposal clarifies the MMSR requirement that broken seals are to be included in the calculation of Item 5-Pasteurization Equipment Tested at Required Frequency (Not required for aseptic milk plants.) on FORM FDA 2359j, Section B-Report of Enforcement Methods (Page 2) when calculating an Enforcement Rating for milk plants when conducting ratings and check ratings.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

The PMO requires Regulatory Agencies to immediately follow up on all milk plant notifications to the Regulatory Agency of a regulatory seal being broken and removed, which would include the required testing and re-sealing of the applicable pasteurization equipment.

Historically, FDA has interpreted Item 5-Pasteurization Equipment Tested at Required Frequency (Not required for aseptic milk plants.) on FORM FDA 2359j, Section B-Report of Enforcement Methods (Page 2) to include within the wording "required frequency" the required Regulatory Agency testing and re-sealing of pasteurization equipment following a milk plant's notification to the Regulatory Agency of a regulatory seal being broken and removed. Even though the current examples used in the MMSR do not specifically cited broken seals, it has been FDA's long standing interpretation and practice while conducting certifications and re-certifications of Sanitation Rating Officers (SROs) to provide this information and guidance to the candidates. This requirement to include broken seals within the calculation of Item 5 has also been taught for numerous years at FD577 Special Problems in Milk Protection courses that are specifically geared to the maintenance of the certification of SROs.

By adding the requirement to include broken seals in the examples cited in the MMSR related to the calculation of Item 5-Pasteurization Equipment Tested at Required Frequency (Not required for aseptic milk plants.) for Enforcement Ratings, we are hoping that this will alleviate any confusion that SROs may have related to what shall be included in these calculations.

C. Proposed Solution

Changes to be made on page(s): 20, 50, 86 & 87 of the (X - one of the following):

	2011 PMO		2011 EML
X	2011 MMSR		2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

MAKE THE FOLLOWING CHANGES TO THE 2011 MMSR:

~~Strike through~~ text to be deleted and <u>underline</u> text to be added.

D. COMPUTATION OF ENFORCEMENT RATINGS …

Page 20:

b. Milk Plant with an Unattached Supply of Raw Milk …

For Example: For ~~an~~ Enforcement ~~Rating~~ <u>Ratings</u>, all required <u>pasteurization equipment</u> tests, <u>including the test(s) required following a milk plant's notification to the Regulatory Agency of a regulatory seal(s) being broken and removed,</u> shall be performed on each individual <u>vat</u> pasteurizer <u>and/or pasteurization system (unit)</u> used to receive credit. Compliance is determined by multiplying the number of <u>vat</u> pasteurizers <u>and/or</u> <u>pasteurization systems</u> (units) by the number of three (3) month periods (quarters)<u>; plus the number of milk plant notifications to the Regulatory Agency of a regulatory seal(s) being broken and removed</u> in the rating period. If a <u>milk</u> plant ~~with~~ <u>utilizes</u> four (4) ~~pasteurizers~~ <u>pasteurization systems (units) and</u> ~~is~~ <u>was last</u> rated ~~over a~~ two (2) ~~year~~ <u>years</u> ~~span~~ <u>ago</u> and one (1) ~~pasteurizer~~ <u>pasteurization system (unit)</u> ~~is not completely tested~~ <u>does not have all of the required tests properly completed</u> during one (1) quarter~~,~~<u>; plus there were four (4) milk plant notifications to the Regulatory Agency of a regulatory seal(s) being broken and removed, of which one (1) did not have the required test(s) conducted before being re-sealed by the Regulatory Agency,</u> then compliance is calculated as follows:

4 <u>(Units)</u> X 8 <u>(Quarters)</u> = 32 Unit (Quarters), Less One (1) Non-Complying Quarter = ~~31/32 X 15 = 14.5~~ <u>Thirty-one (31) of the Total Thirty-two (32) Quarterly Tests are in Compliance; Plus Four (4) Milk Plant Notifications, Less One (1) Non-Complying Testing = Three (3) of the Total Four (4) Milk Plant Notifications are in Compliance for a Total of Thirty-four (34) of Thirty-six (36) in Compliance =</u>

34/36 = 94.4% X 15 Weight = 14.17 Credits.

NOTE: For rating purposes, to determine if the required quarterly pasteurization equipment tests have been performed at the required frequency, the interval shall include the designated period plus the remaining days of the month in which the quarterly pasteurization equipment ~~test(s) is~~ tests are due. …

EXAMPLES OF HOW TO PROPERLY COMPLETE RATING, NCIMS HACCP LISTING, AND ASEPTIC PROCESSING AND PACKAGING PROGRAM LISTING FORMS …

Page 50:

FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (*EXAMPLE: MILK PLANT ONLY*)

REMARKS

5. Two (2) of ~~8~~ eight (8) tests were not completed properly, which included one (1) reported broken seal not being re-tested. …

APPENDIX A.

GUIDELINES FOR COMPUTING ENFORCEMENT RATINGS
(FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2)) …

PART II. MILK PLANTS …

Page 86:

5. Pasteurization equipment tested at required frequency, includes the test(s) required following a milk plant's notification to the Regulatory Agency of a regulatory seal(s) being broken and removed (*Grade "A" PMO*, Section 7 -STANDARDS FOR MILK AND MILK PRODUCTS and APPENDIX I. – PASTEURIZATION EQUIPMENT AND CONTROLS-TESTS). Prorate by the number of vat pasteurizers and/or pasteurization systems ~~units~~ (units) per quarter that were correctly tested; plus the number of milk plant notifications to the Regulatory Agency of a regulatory seal(s) being broken and removed within the required testing frequency ~~vs.~~ divided by the total number of vat pasteurizers and/or pasteurization systems ~~units~~ (units); plus the total number of milk plant notifications to the Regulatory Agency of a regulatory seal(s) being broken and removed. …

a. ~~Total required tests performed based on pasteurization system(s) equals the # number of Vat Pasteurizers, plus the number of HTST Pasteurizers, plus the number of HHST Pasteurizers, plus the number of APPS, if applicable as cited above, at the milk plant.~~

Total required tests performed based on the number of vat pasteurizers and/or pasteurization

systems (units), as applicable, plus the number of milk plant notifications to the Regulatory Agency of a regulatory seal(s) being broken and removed:

# of Vat Pasteurizers + # of HTST Pasteurization Systems (Units) + # of HHST Pasteurization Systems (Units) + # of Ultra-Pasteurization Systems (Units) + # of Aseptic Processing and Packaging Systems (APPSs), if applicable as cited in the **NOTE** above + # of Milk Plant Notifications to the Regulatory Agency of a Regulatory Seal(s) Being Broken and Removed for each Vat Pasteurizer and/or Pasteurization System (Unit) at the milk plant.

For Example:

~~***** = # of three (3) month periods X # of pasteurizers properly checked within each period # of ;three (3) month periods X Total # of pasteurizers~~

***** = # of three (3) month periods (quarters) X # of vat pasteurizers and/or pasteurization systems (units) in which all of the required tests have been properly completed within each three (3) month period; plus the # of milk plant notifications to the Regulatory Agency of a regulatory seal(s) being broken and removed per vat pasteurizer and/or pasteurization systems (units) in which the required test(s) have been properly completed prior to being re-sealed by the Regulatory Agency; divided by the # of three (3) month periods (quarters) X total # of vat pasteurizers and/or pasteurization systems (units); plus the # of milk plant notifications to the Regulatory Agency of a regulatory seal(s) being broken and removed. The last rating was conducted two (2) years ago.

Eight (8) Quarters X Four (4) Units = 32 Unit (Quarters), Less One (1) Non-Complying Quarter for One (1) of the Four (4) Units = Thirty-one (31) of the Total Thirty-two (32) Quarterly Tests are in Compliance; Plus Four (4) Milk Plant Notifications. Less One (1) Non-Complying Testing = Three (3) of the Total Four (4) Milk Plant Notifications are in Compliance for a Total of Thirty-Four (34) of Thirty-six (36) in Compliance =

34/36 = 94.4% X 15 Weight = 14.17 Credits.

Page 87:

***NOTE:** ~~No credit for a period is~~ Credit shall not be given for a vat pasteurizer(s) and/or a pasteurization ~~unit~~ system(s) (unit(s)) unless all of the required tests for ~~that unit~~ an individual vat pasteurizer and/or pasteurization system (unit), including the test(s) required following a milk plant's notification to the Regulatory Agency of a regulatory seal(s) being broken and removed, have been ~~correctly~~ properly completed and recorded.

b. ~~Test~~ Tests shall be performed at the required frequency, including ~~semi-annual and~~ quarterly and semi-annual tests conducted by the Regulatory Agency, ~~and~~ daily tests conducted by ~~an operator~~ milk plant personnel and tests conducted by the Regulatory Agency following a milk plant's notification to the Regulatory Agency of a regulatory seal(s) being broken and removed.

NOTE: ~~Use~~ For the required quarterly and semi-annual testing use *Methods*, Section D., 4.,

a.1.) as a guide: "…the interval shall include the designated period plus the remaining days of the month in which the test(s) is due."

c. All required tests ~~made~~ shall be properly conducted and ~~properly~~ the individual test results, including all required calculations, shall be recorded ~~(required calculations available)~~ on appropriate forms. (Refer to Appendix M of the *Grade "A"* PMO.) The results shall also be entered on appropriate ledger forms. A computer or other information retrieval system may be used.

NOTE: In the case of HACCP listed milk plants that utilize industry personnel, acceptable to the Regulatory Agency, for the testing and sealing of pasteurization equipment, credit shall not be given unless all of the applicable requirements cited in Item 16p.(D)-Pasteurization Records, Equipment Tests and Examinations of the *Grade "A"* PMO are met.

In the case of a Regulatory Agency authorizing on an emergency basis, an industry temporary testing and sealing program, credit shall not be given unless all of the applicable requirements cited in Item 16p.(D)-Pasteurization Records, Equipment Tests and Examinations of the *Grade "A"* PMO are met. …

NOTE: *This Proposal shall take immediate effect upon the issuance of the IMS-a, Actions from the 2013 National Conference on Interstate Milk Shipments, following FDA's concurrence with the NCIMS Executive Board.*

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34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	214
Committee:	MMSR

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This Proposal eliminates Item 7-Milking Time Inspection Program Established from Part I-Dairy Farm on FORM FDA 2359j-Section B-Report of Enforcement Methods (Page 2) and redistributes the five (5) points to Item 8-At Least Four (4) Samples Collected from each Dairy Farm's Supply Every Six (6) Months and all Necessary Laboratory Examinations Made.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

FDA previously submitted a Proposal to the NCIMS Conference to establish the guidelines for a Milking Time Inspection Program and it was defeated by the State voting delegates. Since that time, neither the Methods Committee nor the NCIMS Conference has addressed the issue. Without any resolution to the establishment of guidelines for a Milking Time Inspection Program and the continuance of Regulatory Agencies to receive full credit for this Item on Enforcement Ratings it is warranted to eliminate this Item from FORM FDA 2359j-Section B-Report of Enforcement Methods (Page 2) and redistributes the five (5) points.

C. Proposed Solution

Changes to be made on page(s): iv, v, 31-33, 47, 48, 50, 51, 53-55, 57-60, 77, 81, 82, 84, 85, 92 & 93 of the (X - one of the following):

	2011 PMO		2011 EML
X	2011 MMSR		2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

MAKE THE FOLLOWING CHANGES TO THE 2011 MMSR:

~~Strike through~~ text to be deleted and underline text to be added.

Page iv:

Page v:

Pages 31, 50, 53, 57, 59 and 77:

FORM FDA 2359j-SECTION B-REPORT OF ENFORCEMENT METHODS (PAGE 2)

DAIRY FARMS
PART I

6 Water samples tested and reports on file as required
~~7 5 Milking time inspection program established 5~~
~~8~~7 6 At least four (4) samples collected from each dairy farm's milk supply every six (6) months and all necessary laboratory examinations made ~~10~~ 15

Renumber remaining Items accordingly.

FORM FDA 2359j (10/~~11~~13) (PAGE 2)

Page 53:

DAIRY FARMS
PART I

~~8~~7 6 At least four (4) samples collected from each dairy farm's milk supply every six (6) months and all necessary laboratory examinations made 25 20 80 ~~10~~ 15 ~~8~~ 12

TOTAL CREDIT, PART I ~~90.4~~ 89.4

Under REMARKS

~~8~~7. Insufficient number of samples collected from five (5) dairy farms. (Producer #2, 8, 12, 15 and 19)

Renumber 9, 10 and 11 under REMARKS for DAIRY FARMS PART I accordingly.

INDIVIDUAL SHIPPER RATING
PART III

1 Enter Total Credit from Part I under Percent Complying ~~90.4~~ 89.4 47 ~~42.5~~ 42.02

INDIVIDUAL SHIPPER ENFORCEMENT RATINGS ~~91.2~~ 90.72

Page 57:

ENFORCEMENT RATING ~~76~~ 71

DAIRY FARMS
PART I

~~8~~7 6 At least four (4) samples collected from each dairy farm's milk supply every six (6) months and all necessary laboratory examinations made 1 0 0 ~~10~~ 15 0

TOTAL CREDIT, PART I ~~75.85~~ 70.85

Under REMARKS

~~8~~7. Insufficient number of samples were collected and analyzed (July-December ~~2011~~ 2013)

Renumber 9, 10 and 11 under REMARKS accordingly.

Page 59:

DAIRY FARMS
PART I

~~8~~7 6 At least four (4) samples collected from each dairy farm's milk supply every six (6) months and all necessary laboratory examinations made 25 23 92 ~~10~~ 15 ~~9.2~~ 13.8

TOTAL CREDIT, PART I ~~90.4~~ 90

Under REMARKS

~~8~~7. Insufficient samples from two (2) dairy farms. (Producer #3 and 20)

Renumber 9, 10 and 11 under REMARKS accordingly.

Pages 32, 51 and 54:

FORM FDA 2359j-SECTION C-EVALUATION OF SAMPLING PROCEDURES (PAGE 3)

For the Calculation of DAIRY FARM SAMPLING PROCEDURES (Refer to Part I, Item ~~9~~ 8 on PAGE 2 of this Form)

FORM FDA 2359j (10/~~11~~13) (PAGE 3)

Pages 33, 55, 58 and 60:

FORM FDA 2359j-SECTION D-DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALAUTIONS (PAGE 4)

For the Calculation of DAIRY FARM ENFORCEMENT PROCEDURES (Refer to Part I, Item ~~10~~ 9 on PAGE 2 of this Form)

TOTAL CREDIT to be entered into PART I, Item ~~10~~9 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.

For the Calculation of DAIRY FARM RECORDS (Refer to Part I, Item ~~11~~ 10 on PAGE 2 of this Form)

TOTAL CREDIT to be entered into PART I, Item ~~11~~10 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.

FORM FDA 2359j (10/~~11~~13) (PAGE 4)

Page 47:

6. FORM FDA 2359j- MILK SANITATION RATING REPORT-SECTION C. EVALUATION OF SAMPLING PROCEDURES (PAGE 3) (*EXAMPLE: MULTIPLE FARM BTU AND RECEIVING STATION*) (Used to Complete FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), Part I, Item ~~9~~8 and Part II, Item 8).....
7. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4) (*EXAMPLE: MULTIPLE FARM BTU*) (Used to Complete FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), Part I, Items ~~10~~9 and ~~11~~10) .....

10. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY

FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4) (*EXAMPLE: SINGLE FARM BTU*) (Used to Complete FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), Part I, Items ~~10~~9 and ~~11~~10) .....

Page 48:

12. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4) (*EXAMPLE: MULTIPLE FARM BTU*) (Used to Complete FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), Part I, Items ~~10~~9 and ~~11~~10) .....

Page 81:

~~7. Milking Time Inspection Program established (*Grade "A" PMO*, Section 5 - INSPECTION OF DAIRY FARMS and Section 6 - EXAMINATION OF MILK AND MILK PRODUCTS). All or nothing Item.~~

~~**NOTE:** Until FDA guidance is developed for a Milking Time Inspection Program; full credit is given for this Item.~~

~~8~~7. At least four (4) samples collected in at least four (4) separate months from each dairy farm's milk supply, during any consecutive six (6) months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days, and all necessary laboratory examinations made (*Grade "A" PMO*, Section 6 – EXAMINATION OF MILK AND MILK PRODUCTS). Prorate by number of farms in compliance.

Renumber 9, 10, and 11 under PART I. DAIRY FARMS accordingly.

Page 82:

9. Sampling procedures approved by PHS/FDA evaluation methods (*Grade "A" PMO*, Section 6 - EXAMINATION OF MILK AND MILK PRODUCTS; *EML*; and STANDARD METHODS FOR THE EXAMINATION OF DAIRY PRODUCTS (*SMEDP*)).

NOTE: Use *Methods,* "GUIDANCE FOR COMPUTING ENFORCEMENT CREDIT FOR PART I, ITEM ~~9~~8 AND/OR PART II, ITEM 8 OF FORM FDA 2359j-MILK SANITATION RATING REPORT, SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2)". …

8. Sampling procedures approved by PHS/FDA evaluation methods (*Grade "A" PMO*, Section 6 - EXAMINATION OF MILK AND MILK PRODUCTS; *EML*; and *SMEDP*).

Page 84:

Category IV: Permit Reinstatement …

For Example: FORM FDA 2359j-PART I, Item ~~10~~9 Calculation (Use FORM FDA 2359j-

MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4). (Refer to Section G, #4 for an example of the Form.) …

	Number Inspected	Number Complying	Percent Complying	Weight	Credit
Category I	25	25	100	20	20
Category II	25	22	88	20	17.6
Category III	25	25	100	20	20
Category IV	25	25	100	20	20
Category V	25	25	100	20	20
				TOTAL CREDIT ►	97.6 = 98

TOTAL CREDIT to be entered into PART I, Item ~~10~~9 "Percent Complying" column of FORM FDA 2359j. (Refer to Section H, #s 5, 9 and 11 for examples.)

11. Records systematically maintained and current (*Grade "A" PMO*, Section 3 - PERMITS, Section 5 - INSPECTION OF DAIRY FARMS, Section 6 - EXAMINATION OF MILK AND MILK PRODUCTS, and Section 7 - STANDARDS FOR MILK AND MILK PRODUCTS). ...

Page 85

For Example: FORM FDA 2359j-PART I, Item ~~11~~10 Calculation (Use FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4). (Refer to Section G, #4 for an example of the Form.)

	Number Inspected	Number Complying	Percent Complying	Weight	Credit
Category I	25	25	100	25	25
Category II	25	25	100	25	25
Category III	25	23	92	25	23
Category IV	25	25	100	25	25
				TOTAL CREDIT ►	98

TOTAL CREDIT to be entered into PART I, Item ~~11~~10 "Percent Complying" column of FORM FDA 2359j. (Refer to Section H, #s 5, 9 and 11 for examples.) …

Page 92:

NOTE: Use *Methods,* "GUIDANCE FOR COMPUTING ENFORCEMENT CREDIT FOR PART 1, ITEM ~~9~~8 AND/OR PART II, ITEM 8 OF FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2). …

Page 93:

GUIDANCE FOR COMPUTING ENFORCEMENT CREDIT FOR PART I, ITEM ~~9~~8 AND/OR PART II, ITEM 8 OF FORM FDA 2359j-MILK

SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2)

FORM FDA 2359j-MILK SANITATION RATING REPORT- SECTION C. EVALUATION OF SAMPLING PROCEDURES (PAGE 3) is used to determine enforcement credit for Part I, Item ~~9~~8, FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (Dairy Farms), and Part II, Item 8, FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (Milk Plant). Items 4 and 7 on FORM FDA 2359j-MILK SANITATION RATING REPORT- SECTION C. EVALUATION OF SAMPLING PROCEDURES (PAGE 3) do not apply when calculating Enforcement Ratings for milk plants, receiving and transfer stations for FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), Part II, Item 8.

NOTE: *This Proposal shall take immediate effect upon the issuance of the IMS-a, Actions from the 2013 National Conference on Interstate Milk Shipments, following FDA's concurrence with the NCIMS Executive Board.*

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34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	215
Committee:	Lab

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

Provides pertinent changes to the 2011 Evaluation of Milk Laboratories (EML).

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

The 2011 EML has inconsistent wording that needs to be fixed and some editorial changes. In addition, the sample reports at the end of the document need to be amended to be more relevant to the LEOs and other readers. A revised FDA Template is substituted for the previous editions.

C. Proposed Solution

Changes to be made on page(s): All of the (X - one of the following):

	2011 PMO	X	2011 EML
	2011 MMSR		2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

MAKE THE FOLLOWING CHANGES TO THE 2011 EML:

~~Strike through~~ text to be deleted and underline text to be added.

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PREFACE

In 1941 the United States Public Health Service began evaluations of the facilities, procedures and techniques of analysts in state and local milk laboratories doing official analysis. In 1977, the Food and Drug Administration (FDA) and 46 States had programs for measuring analyst performance in official and officially designated milk laboratories, by on-site ~~evaluations~~ surveys of techniques and proficiency testing. Today all 50 States, Puerto Rico and the Virgin Islands participate in the National Conference on Interstate Milk Shipments (NCIMS) Milk Laboratory Program. These evaluations have resulted in greater uniformity, accuracy and precision of microbiological and chemical analysis.

The material in this publication provides the procedures for the evaluation of milk laboratories required to meet the sanitation standards of the current ~~in use~~ edition of the ~~Grade 'A'~~ Grade "A" Pasteurized Milk Ordinance (PMO).

The information in this booklet was revised by the ~~Food and Drug Administration~~ FDA Laboratory Proficiency Evaluation Team (FDA/LPET) in conjunction with the NCIMS and its Laboratory Committee. The basic responsibility for preparation of this revision was assumed by the ~~Food and Drug Administration~~ FDA, Center for Food Safety and Applied Nutrition, Office of Food Safety, Division of Food Processing Science and Technology, Laboratory Proficiency and Evaluation Team, HFH-450, 6502 South Archer Road, Bedford Park, IL 60501, USA (Telephone (708) 728-4114; Fax (708) 728-4179), hereafter referred to as the FDA/LPET.

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EVALUATION OF MILK LABORATORIES
2011 Revision

INTRODUCTION

Official accreditation of milk laboratories and Certified Industry Supervisors (~~CIS~~ CISs) requires that the appropriate ~~Federal~~ FDA/LPET or State milk laboratory control agency conduct an on-site survey to determine satisfactory performance of analysis in milk laboratories and performance of analysis by ~~CIS~~ CISs in facilities where the examinations, required by the ~~*Grade 'A'*~~ *Grade "A" Pasteurized Milk Ordinance* (PMO), are performed. In addition, satisfactory performance in the analysis of annual proficiency test samples ~~must~~ shall be demonstrated. An accredited milk laboratory may be an approved official or officially designated milk laboratory

under the administrative control of a federal, state or local regulatory authority. Approval of Industry Supervisors (~~IS~~ ISs) and Industry Analysts (~~IA~~ IAs) requires verification of proficiency in performing drug residue analysis at least biennially, through ~~on-site performance~~ laboratory evaluations and/or performance evaluations by analysis of split samples or by other means as noted in SECTION 1 below.

~~The~~ State Laboratory Evaluation Officers (State LEO) certified by the FDA/LPET ~~will~~ shall use the appropriate FDA-2400 Series Forms when evaluating official laboratories, officially designated laboratories, ~~CIS~~ CISs, ~~IS~~ ISs and ~~IA~~ IAs. The ~~Federal~~ FDA/LPET Laboratory Evaluation Officers (~~Federal~~ FDA/LPET LEO) ~~will~~ shall use the appropriate FDA-2400 Series Forms when evaluating State Central Milk Laboratories and State LEOs. Appropriate FDA-2400 Series Forms are those forms that have been approved by the NCIMS Laboratory Committee working cooperatively with the ~~Food and Drug Administration (FDA)~~ FDA and the NCIMS Executive Board, and are effective 90 days after executive board approval. Approved forms shall be issued within 90 days of NCIMS Executive Board approval. If the FDA is unable to release the approved forms within the 90 day time frame, the FDA/LPET shall issue a draft version of the 2400 series forms 90 days after NCIMS Executive Board approval.

Official Laboratory: An official laboratory is a biological, chemical or physical laboratory which is under direct supervision of the state or a local regulatory agency.

State Central Milk Laboratory: A State owned and operated Official Laboratory with analysts employed by the State working in conjunction with the State Regulatory Agency designated as the primary State laboratory for the examination of producer samples of ~~Grade 'A'~~ Grade "A" raw and commingled raw milk for pasteurization, pasteurized milk and milk products, and dairy waters, as necessary.

Officially Designated Laboratory: An officially designated laboratory is a commercial laboratory authorized to do official work by the regulatory agency, or a milk industry laboratory officially designated by the regulatory agency for the examination of producer samples of ~~Grade 'A'~~ Grade "A" raw milk for pasteurization and commingled milk tank truck samples of raw milk for drug residues.

Certified Industry Supervisor (CIS): An industry supervisor who is evaluated and listed by a State LEO as certified to conduct drug residue screening tests at industry drug residue screening

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sites for PMO, Appendix N regulatory actions (confirmation of tankers, producer trace back and/or permit actions).

Industry Supervisor~~s~~ (IS): An individual trained by the State LEO who is responsible for the supervision and training of industry analysts who test milk tank trucks for Appendix N drug residue requirements.

Industry Analyst (IA): A person under the supervision of the CIS or IS who is assigned to conduct screening of milk tank trucks for Appendix N drug residue requirements.

BactoScan Industry Operator (BIO): A person who operates a BactoScan FC under the supervision of a certified BactoScan analyst and analyzes samples for regulatory compliance.

~~Food and Drug Administration (FDA)~~ The FDA laboratory accreditation procedures provide a national base for the uniform collection and examination of milk, in compliance with the sanitation standards of the PMO.

Uniform accreditation of milk laboratories is maintained by the following two functions:

1. FDA accreditation of state central milk laboratories and certification of analysts is based on (a) satisfactory triennial on-site ~~evaluations~~ survey of laboratory facilities, equipment, records, and analyst performance of techniques, and (b) satisfactory annual proficiency testing (the examination of split milk samples) to continuously appraise analyst performance.

2. FDA certification of State LEOs who (1) accredit local laboratories and certify analysts and ~~CIS~~ CISs based on (a) satisfactory biennial on-site ~~evaluations~~ survey of laboratory facilities, equipment, records and analyses and (b) satisfactory annual proficiency testing which meets established national standards and (2) approve ~~IS~~ ISs and ~~IA~~ IAs (who only screen for drugs) based on (a) verification that each IS has been trained (by conducting required workshops for all industry supervisors) and has established a program that ensures the proficiency of the ~~IA~~ IAs they supervise, (b) verification that each IS and IA has demonstrated proficiency in performing drug residue analysis at least biennially. Verification of proficiency may include an analysis of split samples and/or an on-site performance evaluation or another proficiency determination that the State LEO and the FDA/LPET agree is appropriate. (PMO, Appendix N)

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SECTION 1: LABORATORY EVALUATION PROGRAMS

An evaluation of a milk laboratory ~~must~~ shall include an on-site ~~visit~~ survey ~~to~~ of the laboratory, a review of the records, including training records of IAs, records of split sample performance, facilities, equipment, materials and procedures. The evaluation shall be made using the most recent approved Official Milk Laboratory Evaluation Forms (FDA-2400 Series Forms). The ~~Federal~~ FDA/LPET or State LEO shall determine if the laboratory facilities, equipment, records and techniques of analysts are in compliance with the FDA-2400 Series Forms.

A copy of the ~~Grade 'A'~~ "Grade "A" Milk Laboratory Evaluation Request and Agreement Form" (see page 20) ~~must~~ shall be signed by a representative of the facility prior to the initiation of the on-site survey. This document ~~must~~ shall be maintained on file by the ~~Federal~~ FDA/LPET or State LEO.

A set of completed evaluation forms may accompany the narrative report ~~which~~ that describes the degree of suitability of the laboratory facilities, equipment, records, the analysts' procedures, and a statement as to whether the results of the analyst or CIS examinations are acceptable for use in rating milk for interstate shipments. The narrative report ~~must~~ shall be sufficiently detailed to allow readers to determine what is being cited without having to refer to the FDA-2400 Series Forms.

~~Survey reports of on-site evaluations~~ Reports of on-site surveys of Official Milk Laboratories and CISs shall be sent within 60 days of the initial, biennial/triennial anniversary or supplemental date of the laboratory evaluation to the Official Milk Laboratory/CIS, the appropriate ~~Food and Drug Administration~~ FDA Regional Office and the FDA/LPET. Reports can be submitted by traditional fashion (mail, common courier) or electronically. Reports to the Official Milk Laboratories/CIS ~~must~~ shall include the narrative report and may include copies of the completed FDA-2400 Series Forms. Reports to an FDA Regional Office and the FDA/LPET shall be sent electronically and shall include the narrative report and appropriate, completed FDA summary template only (see page 37 – 40).

~~Survey~~ ~~reports~~ Reports of on-site ~~evaluations~~ surveys of screening sites shall be sent to the facility within 60 days of the initial, biennial anniversary, or supplemental date of the laboratory ~~evaluation~~ survey.

CERTIFICATION/APPROVAL OF MILK LABORATORY ANALYSTS

Certification of milk laboratory analysts by the FDA/LPET ~~Federal~~ or State LEO shall be based on the following criteria:

1. Evaluations of State central milk ~~laboratories' evaluations~~ laboratories shall be scheduled and performed by their triennial expiration date. State central milk laboratories shall submit requests, in writing, for an on-site ~~evaluation~~ survey of a new analyst(s) performance of techniques, new methods and/or new facilities to the FDA/LPET. The ~~Federal~~ FDA/LPET LEO shall schedule a mutually agreeable date within 30 days of the request for an evaluation.

2. Evaluations of other milk laboratories within a state shall be scheduled and performed by their biennial expiration date. Milk laboratories within a state shall submit requests, in writing, for on-site ~~evaluation~~ surveys of new analyst(s) performance of techniques, new methods and/or new

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facilities to the State LEO. The State LEO shall schedule a mutually agreeable date within 30 days of the receipt of the request for an evaluation.

3. The laboratory facilities, equipment and records shall meet the requirements stated on the FDA-2400 Series Forms, as determined by an on-site ~~evaluation~~ survey.

4. Analyst performance is in compliance during an on-site ~~evaluation~~ survey, with procedures required by the FDA-2400 Series Forms and the PMO.

5. Analysts meet the performance levels of the proficiency testing program (SECTION 2). The State LEO may issue a certificate of approval to each laboratory analyst who meets the stated criteria in numbers 3 and 4 above. The certificate, if issued, shall indicate the specific laboratory procedure(s) for which he or she is certified or approved.

6. Vitamin testing laboratories have submitted satisfactory quality control information, use methods acceptable to the FDA or other official methodologies which give statistically equivalent results to the FDA methods, have one or more certified analysts who have satisfactorily participated in the vitamin split sample program and have met performance levels of the proficiency testing program (SECTION 2).

Analysts seeking certification or approval who are employed in laboratories not previously approved, or laboratories that have lost accreditation or approval and are seeking Recertification, may be approved to conduct official examinations only if criteria 3 and 4 above are met. When such analysts successfully complete the next official proficiency tests administered by the State LEO, a certificate of approval may be issued to such analyst. If such analyst does not successfully meet the performance levels of the proficiency testing program, the approval to conduct official examinations shall be withdrawn.

When a new analyst is assigned to an accredited laboratory between on-site ~~evaluations~~ surveys, conditional approval status ~~will~~ shall be provided to the new analyst upon satisfactory completion of criteria 4 or 5 above. Full certification ~~will~~ shall follow after acceptable completion of both criteria 4 and 5 above. Conditionally approved analysts failing to meet the established applicable criteria of laboratory performance during an on-site laboratory ~~evaluation~~ survey ~~will~~ shall have their conditionally approved status revoked.

The ~~CIS~~ CISs and certified analysts ~~must~~ shall participate, at least annually, in proficiency testing (the examination of milk split samples) for those specific procedures for which they are certified. Failure without cause to participate in the annual split samples ~~evaluation~~ or failure to meet established satisfactory performance criteria ~~will~~ shall result in the ~~CIS~~ CIS(s) or certified analyst(s) having their certification status downgraded from full to provisional. Failure of a provisionally certified analyst or CIS to participate in the examination of or to meet established satisfactory performance levels on the next set of split samples ~~will~~ shall result in withdrawal of their certification.

A CIS or certified analyst that loses their certification for one or more tests cannot examine official samples using a test for which their certification was withdrawn. Recertification procedures are shown in "SECTION 2: PROFICIENCY TESTING PROGRAMS".

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Copies of notices of changes of certification or revocation of certification shall be sent to the laboratory or facility involved, the milk regulatory agency, the state milk sanitation rating

agency, the appropriate FDA Regional Office and the FDA/LPET. For FDA/LPET notification, changes in certification shall be indicated on the appropriate, completed FDA summary template and shall be submitted electronically.

Upon notice of revocation, the certificate, if issued, shall be returned to the issuing State LEO within 90 days.

ACCREDITATION/APPROVAL OF MILK LABORATORIES

Accreditation or approval of milk laboratories by ~~Federal~~ the FDA/LPET or State milk laboratory control agencies shall be based on meeting the following requirements:

1. The laboratory facilities, equipment, procedures and records ~~must~~ shall meet the requirements stated on the appropriate FDA-2400 Series Forms and for ~~CIS~~ CISs, appropriate Appendix N 2400 Series Forms, as determined by an on-site ~~evaluation~~ survey.

2. All official examinations required by the PMO ~~must~~ shall only be performed by certified analysts or ~~CIS~~ CISs.

3. Vitamin testing laboratories have submitted satisfactory quality control information, use methods acceptable to the FDA or other official methodologies which give statistically equivalent results to the FDA methods, have one or more certified analysts who have satisfactorily participated in the vitamin split sample program and have met performance levels of the proficiency testing program (SECTION 2).

The State LEO may issue a certificate of accreditation or approval to each official, commercial, and industry laboratory meeting criteria 1 and 2 above. The certificate shall be valid for 2 years unless revoked.

When an accredited laboratory changes location or undergoes substantial remodeling, ~~an evaluation~~ a survey of the new laboratory or screening facility is required within 3 months. ~~No evaluation~~ A survey of personnel or procedures is not required at this time.

For initial accreditation, milk laboratories shall have a minimum of 15 days of required records available at the time of the on-site ~~evaluation~~ survey. The laboratory has records to show that all necessary quality control requirements have been performed and are satisfactory, and that there are 15 days of records to demonstrate that critical equipment is functional.

When a certified analyst or CIS leaves an accredited laboratory, the laboratory/facility manager ~~must~~ shall notify the ~~Federal~~ FDA/LPET or State LEO immediately since the loss of a certified analyst may result in the loss of certification for one or more procedures, or may result in the loss of the laboratory's accreditation. For example, a laboratory having only one certified analyst ~~will~~ shall lose accreditation. Official examinations cannot be conducted at non-accredited laboratories. When a laboratory or CIS facility loses its accreditation because of lack of certified analysts, or for some other reason,

the ~~Federal~~ FDA/LPET or State LEO shall immediately notify the milk laboratory involved, the state milk regulatory agency, the state milk sanitation rating agency, any out-of-state milk regulatory agencies where known customers are located, the appropriate FDA Regional Office and the FDA/LPET, by a letter of notification to be dated within five (5) working days of the loss of accreditation. For any FDA/LPET notification, changes in accreditation shall be indicated on the appropriate, completed FDA summary template and shall be submitted electronically.

Laboratories requesting withdrawal of accreditation shall notify the State LEO in writing. Upon receipt of the written request, the State LEO shall immediately notify the state milk regulatory agency, the state milk sanitation rating agency, any out-of-state milk regulatory agencies where known customers are located, the appropriate FDA Regional Office and the FDA/LPET by a letter of notification to be dated within five (5) working days of receipt of the written request. Upon notice of withdrawal of accreditation, the certificate, if issued, shall be returned to the issuing State LEO within 90 days. For FDA/LPET notification, changes in accreditation shall be indicated on the appropriate, completed FDA summary template and shall be submitted electronically.

State Central Milk Laboratories requesting withdrawal of accreditation shall notify the FDA/LPET in writing and shall notify the appropriate FDA Regional Office in writing within 5 working days of the FDA/LPET's receipt of the written request.

Additionally, the laboratory shall notify its customers in writing, that it has withdrawn or been decertified and shall not represent itself as an official laboratory or officially designated laboratory, for those decertified or unapproved procedures under the agreements of the NCIMS. A copy of the generic notification ~~must~~ shall be sent to the State LEO. Decertification ~~will~~ shall remain in effect until measures are taken by the laboratory to attain compliance and another on-site survey is completed successfully.

APPROVAL OF INDUSTRY ANALYSTS/INDUSTRY SUPERVISORS

Approval of Industry Supervisors (~~IS~~ ISs) and Industry Analysts (~~IA~~ IAs) by the State LEOs shall be based on meeting all of the following requirements:

1. The laboratory facilities, equipment, procedures and records meet the requirements stated on the approved 2400 Series Forms associated with the Appendix N program.

2. All screening tests required by the PMO, Appendix N ~~must~~ shall only be performed by approved ~~IS~~ ISs, ~~IA~~ IAs or by a certified entity.

3. Analyst performance is in compliance with procedures required by the approved FDA-2400 Series Forms associated with the Appendix N program.

4. The analyst meets the performance levels of the proficiency testing program (the examination of milk split samples).

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5. Approval of ~~IS~~ ISs and ~~IA~~ IAs require verification of proficiency in performing drug residue analyses at least biennially, through an on-site ~~performance evaluation~~ survey and/or analysis of split samples, or ~~another proficiency determination~~ by other means of determining proficiency that the State LEO and the FDA/LPET agree is appropriate. (PMO, Appendix N)

6. The IS has attended and received training by the State LEO. This training ~~must~~ shall be documented.

The IS shall report to the State LEO the result of all competency evaluations performed by ~~IA~~ IAs. The name of each IS and IA (as well as their training and ~~evaluation~~ approval status) shall be maintained by the State LEO and updated as replacement, additions and/or removals occur. The State LEO shall verify (document) that each IS has established a program that ensures the proficiency of the ~~IA~~ IAs they supervise. The State LEO shall also verify that each IS and IA has demonstrated proficiency in performing drug residue analysis at least biennially. Verification may include an analysis of split samples and/or an on-site ~~performance evaluation~~ survey or ~~another proficiency determination~~ by other means of determining proficiency that the State LEO and the FDA/LPET agree is appropriate.

When a new analyst is assigned to an approved laboratory, conditional approval status ~~will~~ shall be provided to the new analyst upon satisfactory demonstration of competency to the IS. Full approval status ~~will~~ shall follow after verification of proficiency (see criteria #5, above). Conditionally approved analysts failing to meet the established applicable criteria of laboratory performance during an on-site ~~laboratory evaluation~~ survey or analysis of split samples ~~will~~ shall have their conditionally approved status revoked.

Fully approved analysts failing to meet the established applicable criteria of laboratory performance during an on-site ~~laboratory evaluation~~ survey or analysis of split samples ~~will~~ shall have their fully approved status downgraded to "provisional". Provisionally approved analysts failing to meet the established applicable criteria of laboratory performance during an on-site ~~laboratory evaluation~~ survey or analysis of split samples ~~will~~ shall have their provisionally approved status revoked.

Failure by the ~~IS~~ ISs or the ~~IA~~ IAs to demonstrate adequate proficiency to the State LEO shall lead to their removal from the State LEO list of approved ~~IS~~ ISs /~~IA~~ IAs. Re-instatement of their testing status shall only be possible by completing retraining and/or successfully analyzing split samples and/or passing an on-site ~~evaluation~~ survey or otherwise demonstrating proficiency to the State LEO. Analysts not on the State LEO list of ~~A~~approved ~~IS~~ ISs/~~IA~~ IAs are not approved to test bulk milk in the Appendix N program.

When a screening facility loses its approval because of the lack of approved ~~IS~~ ISs or ~~IA~~ IAs, or for some other reason, the State LEO shall immediately notify the screening facility involved, the state milk regulatory agency, the state milk sanitation rating agency, any out-of-state milk regulatory agencies where known customers are located, the appropriate FDA Regional Office and the FDA/LPET, by a letter of notification to be dated within five (5) working days of receipt

of the loss of their approval. For FDA/LPET notification, changes in approval shall be indicated on the appropriate, completed FDA summary template and shall be submitted by email.

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Screening facilities requesting withdrawal of approval shall notify the State LEO in writing. Upon receipt of the written request, the State LEO shall immediately notify the state milk regulatory agency, the state milk sanitation rating agency, any out-of-state milk regulatory agencies where known customers are located, the appropriate FDA Regional Office and the FDA/LPET by a letter of notification to be dated within five (5) working days of receipt of the written request. For FDA/LPET notification, changes in approval shall be indicated on the appropriate, completed FDA summary template and shall be submitted by email.

Additionally, the screening facility shall notify its customers in writing that it has been withdrawn or has lost its approval and shall not represent itself as an approved screening facility under the agreements of the NCIMS. A copy of the generic notification ~~must~~ shall be sent to the State LEO. Loss of approval ~~will~~ shall remain in effect until measures are taken by the screening facility to attain compliance and another on-site survey is completed successfully.

APPROVAL OF BACTOSCAN INDUSTRY OPERATORS

Approval of BactoScan Industry Operators (BIO) shall be based on meeting the following requirements:

1. The industry operator ~~must~~ shall complete the BIO operating protocols, training and oversight specified in the training procedure document.

2. The laboratory ~~must~~ shall maintain one (1) certified BactoScan analyst (see current FDA 2400 series form) for training and ongoing oversight of the BIO.

3. Refer to the BIO approved training procedures at the end of the BactoScan FDA 2400 series form.

4. The BIO meets the performance levels of the proficiency testing program (the examination of milk split samples)

5. Records are to be maintained for BIO oversight.

NOTE: A BIO can analyze samples for regulatory compliance.

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SECTION 2: PROFICIENCY TESTING PROGRAMS

SPLIT SAMPLES - MICROBIOLOGY

The ~~Food and Drug Administration~~ FDA/LPET shall split samples annually with all ~~federally~~ FDA certified analysts of each State/Territory (hereafter noted as State) central accredited milk laboratory. State milk laboratory control agencies shall split samples at least annually with all state certified analysts of each official, officially designated accredited milk laboratory, and all ~~CIS~~ CISs. State milk laboratory control agencies shall verify that each IS and IA has demonstrated proficiency in performing drug residue analysis at least biennially through ~~on-site performance~~ laboratory evaluation and/or ~~analysis of split samples~~ annual performance evaluation, or ~~another proficiency determination~~ by other means of determining proficiency that the State LEO and the FDA/LPET agree is appropriate.

State milk laboratory control agencies having less than 10 analysts (total) in their milk laboratory program are to develop joint state proficiency testing programs with other states which can meet the criteria for certification of analysts and accreditation of laboratories. In cases where a minimum number of analysts ($\geq$ 10) are not available, evaluation of proficiency ~~will~~ shall be made by a determination that the State LEO and the FDA/LPET agree is appropriate.

An acceptable annual proficiency testing program shall meet the following applicable criteria:

1. When an analyst examines both raw milk for pasteurization and pasteurized milk and milk products, a minimum of twenty-two (22) samples shall be examined by the analyst using those procedures for which the analyst has been approved unless excused for due cause. The laboratory tests, categories, types and recommended duplicates of milk products are shown in Table 1, page 27.

2. When an analyst examines only raw milk for pasteurization, a minimum of fourteen (14) samples shall be examined by the analyst using those procedures for which the analyst has been approved unless excused for due cause. The laboratory tests and recommended duplicates of samples are shown in Table 1, page 27.

3. When an analyst examines only pasteurized milk and milk products, a minimum of sixteen (16) samples shall be examined by the analyst using those procedures for which the analyst has been approved unless excused for due cause. The laboratory tests and recommended duplicates of samples are shown in Table 1, page 27.

4. When a CIS examines bulk milk tanker milk or its equivalent for Appendix N purposes, a minimum of eight (8) samples shall be analyzed utilizing the test kit(s) for which that CIS is certified or approved, or for which the CIS is seeking certification. In general, the milk samples shall consist of the members of the beta-lactam family, at the safe/tolerance levels, which the test kit(s) is designed to detect as well as milk samples that do not contain ~~containing no~~ animal drug residues. The CIS may misidentify one of the samples and maintain and/or gain certification. If more than one (1) sample is misidentified, the CIS falls one (1) level of certification. If this occurs twice consecutively, the CIS is ~~no longer~~ not certified or approved (rules for Recertification of laboratories apply).

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5. When an IS or an IA examines bulk milk tanker milk or its equivalent for Appendix N purposes, a minimum of eight (8) samples shall be analyzed utilizing the test kits for which that IS or IA is approved or for which the IS or IA is seeking approval. In general, the milk samples shall consist of members of beta-lactam family, at the safe/tolerance levels, which the test kits are designed to detect as well as milk samples ~~containing no~~ that do not contain animal drug residues. The IS or IA may misidentify one (1) of the samples and maintain and/or gain approval. If more than one (1) sample is misidentified, the IS or IA falls one (1) level of approval. If this occurs twice consecutively, the IS or IA is ~~no longer~~ not approved. Re-instatement of their testing status shall only be possible by completing retraining and/or successfully analyzing split samples and/or passing an on-site ~~evaluation~~ survey or otherwise demonstrating proficiency to the State LEO.

6. Each analyst certified to perform visual drug residue tests ~~will~~ shall participate in annual proficiency tests to demonstrate their ability to detect the beta-lactams at safe/tolerance level per kit label claim (Penicillin G, Cloxacillin, Ceftiofur, and Cephapirin) using blind samples with duplicate negatives. A minimum of six (6) samples may be used. However, with six (6) samples ALL results ~~must~~ shall be correct. If eight (8) samples are used, an analyst/CIS may miss one (1) and still pass the proficiency test.

7. An acceptable annual proficiency testing program for the BactoScan FC (all NCIMS approved models), shall meet the following applicable criteria.

   (a) The BactoScan FC (all NCIMS approved models) shall be used to examine a minimum of fourteen (14) samples and be operated by a certified analyst or an approved BIO using the procedures approved to operate the BactoScan FC and for which the analyst or BIO has been certified/approved, respectively.
   (b) Split samples (minimum of 14) shall be made up using BactoScan FC Blank solution and BactoScan FC Bacteria Control Samples.
   (c) Value ranges (count ranges) and dilutions shall be made to achieve the levels as set by the FDA. Recommended duplicates of samples are shown in Table 1, page 27.

SPLIT SAMPLE ANALYSIS

The Standard Plate Count (SPC), Petrifilm Aerobic Count (PAC), Plate Loop Count (PLC), BactoScan FC Count (BSC), Spiral Plate Count Method (SPLC), Direct Microscopic Somatic Cell Count (DMSCC), Electronic Somatic Cell Count (ESCC), Electronic Phosphatase Count and Vitamin A and D_3 result of each certified analyst shall fall within the limits shown in Table 2, page 28.

The steps for statistical analysis of split sample results are as follows:

1. A minimum of ten (10) results per sample per test is required for statistical analysis.

2. Calculate the logarithmic mean for the ~~Standard Plate Count~~ SPC, ~~Petrifilm Aerobic Count~~ PAC, ~~Plate Loop Count~~ PLC, ~~BactoScan FC Count (BSC)~~ BSC, ~~Spiral Plate Count Method~~

~~ SPLC)~~ SPLC, ~~Direct Microscopic Somatic Cell Count~~ DMSCC, ~~Electronic Somatic Cell Count~~ ESCC, Electronic Phosphatase

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Count and Vitamin A and D_3 results of each test sample; using a table of common logarithms, list the logarithms of all analyst counts for a given sample. Calculate the mean of the logarithms for the sample.

3. Determine for each sample for each test whether there are results outside of the Rejection Limit (L_1). Rejection results are identified by applying to each analyst's result the limit (sample mean ± L_1). Results falling outside the limit are classified as outliers and are unacceptable. Note by sample and test, the analysts who have results outside of the limits.

4. Determine for each sample for each test whether there are analyst results outside of the Rejection Limit (L_2). Remove unacceptable analyst result and re-compute the mean of each sample if results have been rejected in accordance with 3 above. If there are none, use the same means calculated in 2 or 3 above. Rejection results are identified by applying to each analyst's result the limit (sample mean ± L_2). Results falling outside the limit are classified as "out of limits" and are unacceptable. Note by sample and test, the analysts who have results outside of these limits.

5. Using Table 3, page 26, list all analysts who have more than the maximum number of sample results per test classified as unacceptable by either the L_1 or L_2 or both limits.

6. Analysts certified for vitamin analysis shall meet the acceptance limits (L_1 and L_2) and performance levels shown in Tables 2 and 3, page 28.

7. An acceptable annual proficiency testing program for the BactoScan FC Count (all NCIMS approved models), shall meet the following applicable criteria.

   (a) The BactoScan FC Count (all NCIMS approved models) shall be used to examine a minimum of fourteen (14) samples and be operated by a certified analyst or an approved BIO using the procedures approved to operate the BactoScan FC Count and for which the analyst or BIO has been certified/approved, respectively.
   (b) Split samples (minimum of 14) shall be made up using BactoScan FC Blank solution and BactoScan FC Count Bacteria Control Samples.
   (c) Value ranges (count ranges) and dilutions shall be made to achieve the levels as set by the FDA. Recommended duplicates of samples are shown in Table 1 page 27.

ANALYST PERFORMANCE LEVEL

Analysts certified to perform the examinations required by the ~~Grade 'A'~~ "Grade "A" PMO" shall meet the following performance levels on an annual basis.

1. Analysts certified to perform the ~~Standard Plate Count~~ SPC, ~~Petrifilm Aerobic Count~~ PAC, ~~Plate Loop Count~~ PLC, ~~BactoScan FC~~ BSC, ~~Spiral Plate Count Method~~ SPLC, ~~Direct Microscopic Somatic Cell Count~~ DMSCC, ~~Electronic Somatic Cell Count~~ ESCC, Electronic Phosphatase Count and Vitamin A and D_3 analysis, and BIOs approved to operate a BactoScan FC shall meet the acceptance limits and performance levels shown in Tables 2 and 3, page 28.

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2. Analysts certified to perform inhibitor tests shall detect samples that contain beta-lactam or other animal drug residues detectable by the appropriate official test for the drug and product. If using a drug other than beta-lactam, samples ~~must~~ shall be spiked in duplicate. See Table 3, page 28.

3. Analysts certified to perform phosphatase tests shall detect samples that contain residual phosphatase detectable by appropriate official test methods. Analysts certified for Electronic Phosphatase Count methods shall detect samples that contain between 100 and 2,500 mU (the majority of values at the action level of 350 mU) within the specified limits in Table 2, page 28.

4. Analysts certified for the coliform procedure shall qualitatively detect and verify coliform organisms in samples containing at least five (5) but not greater than ten (10) coliform organisms per milliliter or gram of product. See Table 3, page 28.

5. ~~Certified Industry Supervisors~~ CISs certified to perform Appendix N test(s) for beta-lactam drugs shall detect members of the beta-lactam family, at the safe/tolerance levels, which the test kit(s) is designed to detect. See Table 3, page 28.

Fully certified analysts not meeting the described performance levels shall be provisionally certified for the test procedure(s) in which they exceed the maximum number of unacceptable results on samples. Provisionally certified analysts can regain full certification status by meeting satisfactory performance levels on the next set of split samples. If a provisionally certified analyst does not meet satisfactory performance levels on the next set of split samples, certification to perform the specific test(s) ~~will~~ shall be withdrawn. An analyst who has lost certification may be required to participate in a training program acceptable to the milk laboratory certifying authority before requesting recertification. Recertification after training shall be based on the analyst meeting the certification criteria described in SECTION 1: LABORATORY EVALUATION PROGRAMS. A certified analyst may only become conditionally approved again by the route by which he/she lost certification, i.e. if the analyst lost certification due to failure on milk split samples then he/she can only become conditionally certified by passing the next set of milk split samples. If the analyst failed an on-site survey ~~evaluation~~ that leads to his/her loss of certification then he/she ~~must~~ shall pass the next on-site certification to become conditionally certified.

~~BactoScan Industry Operators~~ BIOs performance levels shall follow the performance procedures indicated above for fully certified analysts.

Copies of the proficiency testing report, including tabulation of analyst results, shall be sent within four (4) months of the split sample examination date to the participating laboratory, the appropriate FDA Regional Office, and the FDA/LPET.

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SPLIT SAMPLES – CHEMISTRY

VITAMINS

The Grade "A" Vitamin Proficiency Test Program is operated by the FDA/LPET. In order to be accredited and be listed, laboratories ~~must~~ shall have analysts who have satisfactorily participated in at least two (2) consecutive split sample analyses and ~~must~~ shall have submitted satisfactory method validation and quality control/quality assurance (QC/QA) information. Participation in proficiency testing alone does not satisfy the criteria for analyst certification and laboratory accreditation.

The Grade ~~A~~ "A" Vitamin Proficiency Testing Program involves the analysis of sets of four (4) samples sent to participating laboratories every four (4) months, i.e., three (3) times a year with a total of twelve (12) samples. Certification status is based in part on the ability of analysts to analyze samples and have their results fall within limits (L_1=0.300 and L_2=0.200, based on the statistical parameters set at the 1995 NCIMS Conference in St. Louis, MO). Conditional certification is granted to an analyst (not to a laboratory) when the analyst has satisfactorily analyzed two (2) sets of samples (eight (8) samples in two (2) consecutive shipments). Analysts may have one (1) unsatisfactory result, i.e., miss (out of limits) one (1) sample, and still be considered as having satisfactory performance. After analyzing the next consecutive set of samples, the analyst is considered fully certified if not more than ~~2~~ two (2) samples have been missed over the course of a one (1) year period (twelve (12) consecutive samples analyzed).

Once fully certified, analysts maintain certification by satisfactorily analyzing all three (3) sets of split samples each year. During the course of the year full certification is maintained if ~~no~~ not more than two (2) samples (of ~~12~~ twelve (12)) are missed. Failure without cause to analyze all twelve (12) samples during the course of the year ~~will~~ shall result in the down grading of an analyst's status. It is imperative that laboratory schedules be set up to allow for the analysis of these samples. If a fully certified analyst misses more than two (2) samples (of ~~12~~ twelve (12)) then that analyst ~~will~~ shall be ~~down graded~~ downgraded to provisional certification. Full certification ~~will~~ shall be regained if that analyst misses ~~no~~ not more than one (1) sample of the next eight (8) that he/she analyzes. Provisionally or conditionally certified analysts that miss more than one (1) sample in the next eight (8) samples analyzed after receiving the respective status ~~will~~ shall have their certification/approval removed.

Once certification/approval is removed an analyst may only regain conditional certification by satisfactory performance on the next eight (8) samples, i.e., miss ~~no~~ not more than one (1) sample. Full certification requires that the analyst meet the criteria described above.

For split sample purposes each analyst ~~must~~ shall independently analyze the samples. Routine analysis may be performed by multiple analysts working together or by partitioning duties. Certified analysts are responsible for conducting official analysis. Non certified analysts may assist in analysis, but may not solely perform official analyses or report official results.

Re-entry of laboratories that have voluntarily withdrawn or laboratories that have had their accreditation removed ~~is~~ are subject to meeting all of the requirements needed from a new laboratory, including all quality control (QC) information. It is the responsibility of the laboratory to inform the FDA/LPET when a certified analyst is ~~no longer~~ not employed at that laboratory. A laboratory

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that loses all of their certified analysts is ~~no longer~~ not accredited to do official work and ~~must~~ shall seek new laboratory entry prior to resuming official analysis.

An acceptable annual proficiency testing program shall consist of the analyst examining pasteurized milk and milk products for Vitamins A and D_3, a minimum of four (4) samples three (3) times a year for a total of twelve (12) samples annually using the methods developed by the FDA, or methods that give statistically equivalent results to the FDA methods, for which the analyst has been approved, unless excused for due cause. The laboratory tests and recommended duplicates of samples are shown in Table 1, page 27.

WATER MICROBIOLOGY

Laboratories using EPA or State administrated programs for water analysis are not required to meet the intentions of this Section. State administered programs include central, official, officially designated and other water testing laboratories sanctioned by the state and participation in a split sample program is voluntary.

Each State central accredited milk laboratory, and all State official, officially designated accredited milk laboratories not participating in an EPA or State administered program for water analysis shall participate annually in a microbiological proficiency testing program for each water analysis methodology for which the laboratory is certified. The proficiency testing samples are to be provided by State programs or through private providers.

An acceptable annual proficiency testing program shall meet the following applicable criteria:

1. When a laboratory examines dairy water for the presence of coliforms, a minimum of eight (8) samples shall be examined by the laboratory using those procedures for which the laboratory has been approved unless excused for due cause. The laboratory tests, categories, types and recommended duplicates are shown in Table 1, page 27.

SPLIT SAMPLE ANALYSIS

The multiple tube fermentation (Lauryl Tryptose Broth or Chromogenic substrate), membrane filtration and heterotrophic plate count result of each laboratory shall fall within the limits shown in Table 2, page 28.

The steps for statistical analysis of split sample results are as follows:

1. A minimum of ten (10) results per sample per test is required for statistical analysis.

2. Calculate the logarithmic mean for the multiple tube fermentation, membrane filtration and heterotrophic plate count for each test sample; using a table of common logarithms, list the logarithms of all counts for a given sample. Calculate the mean of the logarithms for the sample.

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3. Determine for each sample for each test whether there are results outside of the Rejection Limit (L_1). Rejection results are identified by applying to each laboratory's result the limit (sample mean ± L_1). Results falling outside the limit are classified as outliers and are unacceptable. (Note by sample and test, the laboratories that have results outside of the limits.)

4. Determine for each sample for each test whether there are laboratory results outside of the Rejection Limit (L_2). Remove unacceptable laboratory results and re-compute the mean of each sample if results have been rejected in accordance with 3 above. If there are none, use the same means calculated in 2 or 3 above. Rejection results are identified by applying to each laboratory's result the limit (sample mean ± L_2). Results falling outside the limit are classified as "out of limits" and are unacceptable. (Note by sample and test, the laboratories that have results outside of these limits.)

5. Using Table 3, page 26, list all laboratories that have more than the maximum number of sample results per test classified as unacceptable by either the L_1 or L_2 or both limits.

6. Laboratories accredited for dairy water analysis shall meet the acceptance limits (L_1 and L_2) and performance levels shown in Tables 2 and 3, page 28.

LABORATORY PERFORMANCE LEVEL

Laboratories accredited to perform the examinations of dairy water for coliforms required by the PMO shall meet the following performance levels on an annual basis.

1. Laboratories accredited to perform the multiple tube fermentation, membrane filtration, heterotrophic plate count and chromogenic substrate analysis shall meet the acceptance limits and performance levels shown in Tables 2 and 3, page 28.

2. Laboratories accredited for presence-absence procedures shall qualitatively detect and verify coliform organisms in samples containing coliform organisms.

Fully accredited laboratories not meeting the described performance levels shall be provisionally accredited for the test procedure(s) in which they exceed the maximum number of unacceptable results on samples. Provisionally accredited laboratories can regain full accreditation status by meeting satisfactory performance levels on the next set of split samples. If a provisionally accredited laboratory does not meet satisfactory performance levels on the next set of split samples, accreditation to perform the specific test(s) ~~will~~ shall be withdrawn. A laboratory that has lost their accreditation ~~must~~ shall participate in a training program acceptable to the milk laboratory certifying authority before requesting ~~reaccreditation~~ re-accreditation. Re-accreditation after training shall be based on the laboratory meeting the accreditation criteria described in SECTION 1: LABORATORY EVALUATION PROGRAMS.

Copies of the proficiency testing report, including tabulation of laboratory results, shall be sent within four (4) months of the split sample examination date to the participating laboratory, the appropriate ~~Food and Drug Administration~~ FDA Regional Office, and the FDA/LPET.

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SECTION 3: CERTIFICATION OF LABORATORY EVALUATION OFFICERS

Initial certification of a State LEO shall be based on meeting the following criteria:

1. The individual ~~must~~ shall be a State government employee and demonstrate competence in evaluating milk testing laboratories and analysts' performance of milk laboratory test methods or Appendix N procedures as stated on the FDA-2400 Series Forms when accompanied by a representative of the FDA/-LPET on ~~an~~ the initial check ~~laboratory~~ on-site survey(s). The ~~Federal~~ FDA/LPET LEO shall accompany the State LEO to not more than two (2) laboratories/facilities during ~~an~~ the initial check on-site survey(s) for initial certification purposes. Initial check on-site surveys (for certification) should not be conducted at sites that have been evaluated within the past 90 days.

2. The individual ~~must~~ shall submit an acceptable written report of the milk laboratory initial check on-site survey to the FDA/LPET within ~~60~~ sixty (60) days of the ~~evaluation~~ survey. Reports to the appropriate FDA Regional Office and the FDA/LPET shall be sent by email and shall include the narrative report and appropriate, completed FDA summary template only (see pages 37 - 40).

3. The individual ~~must~~ shall attend the Milk Laboratory Evaluation Officers Workshop (FDA Course #FD373) conducted by the FDA/LPET ~~in conjunction with the Food and Drug Administration, State Training Team~~. If the individual does not have experience in the examination of dairy products, they ~~must~~ shall attend Course #FD374 "Laboratory Examination of Dairy Products" prior to or within the year of attending the Milk Laboratory Evaluation Officers Workshop.

NOTE: It is recommended that the individual attend the Milk Laboratory Evaluation Officers Workshop prior to step 1 above.

Laboratory evaluations conducted by conditionally approved State LEOs ~~will~~ shall be considered official.

Conditional certification of a new State LEO can occur following the initial check on-site survey(s) described above. Full certification ~~will~~ shall be granted after the State LEO attends the next scheduled Milk Laboratory Evaluation Officers Workshop. Failure of a conditionally certified State LEO to attend the next scheduled Milk Laboratory Evaluation Officers Workshop, unless excused with cause by the FDA/LPET, ~~will~~ shall require that the State LEO ~~must~~ restart the process. The State LEO candidate would then be required to participate in ~~another~~ a new check on-site survey(s) with a representative of the FDA/LPET, and then attend the next scheduled Milk Laboratory Evaluation Officers Workshop.

Recertification of the State LEO ~~will~~ shall occur triennially, and ~~will~~ shall be based on satisfactorily meeting the following criteria:

1. The individual ~~must~~ shall be a State government employee and demonstrate continued competence in evaluating milk testing laboratories and analysts' performance of milk laboratory test methods or Appendix N procedures as stated on the FDA-2400 Series Forms when accompanied by a representative of the FDA/LPET on a check ~~laboratory~~ on-site survey. The

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~~Federal~~ FDA/LPET LEO shall accompany the State LEO to not more than two (2) laboratories/facilities during a check on-site survey for recertification purposes.

2. The individual ~~must~~ shall submit ~~an~~ acceptable written reports of the milk laboratory check on-site survey(s) to the FDA/LPET within ~~60~~ sixty (60) days of the ~~evaluation~~ survey. Reports to the appropriate FDA Regional Office and the FDA/LPET shall be sent by email and shall include the narrative report and appropriate, completed FDA summary template only (see pages 37 – 40).

3. The individual ~~must~~ shall have all laboratory evaluations, proficiency test examinations, and reports current (in particular, biennial on-site surveys ~~must~~ shall be performed within the month of their anniversary date).

4. The individual ~~must~~ shall have prepared and transmitted, at least annually, a summary list of certified and approved analysts and procedures by laboratory to the state milk sanitation rating agency and the FDA/LPET.

5. The individual has met the responsibilities for the training of ~~Industry Supervisors~~ ISs.

6. The individual ~~must~~ shall attend the Milk Laboratory Evaluation Officers Workshop once every three (3) years.

7. The individual ~~must~~ shall not fail, without cause, to attend an FDA Regional Milk Seminar. If a region holds a FDA Regional Milk Seminar, then State LEOs in that region are obligated to attend. If another region holds their regional milk seminar in the same year the State LEO may opt to attend that regional milk seminar in lieu of attending the regional milk seminar held in their region and still meet the requirement.

Once an individual has become a State LEO and is therefore considered fully certified, if he/she fails to submit acceptable written reports of milk laboratory ~~evaluations~~ on-site surveys within ~~60~~ sixty (60) days to the FDA/LPET or fails to comply with item 2 above for Recertification (or continued certification), the State LEO ~~will~~ shall have ~~their~~ his/her certification status downgraded from full to provisional. In addition, an action plan ~~will~~ shall be established that is mutually agreeable to the FDA/LPET and the state. The State LEO ~~would~~ shall have to meet the action plan criteria in addition to continuing to meet all the criteria specified in items 1-7 above, to maintain provisional certification status.

Laboratory evaluations conducted by provisionally approved State LEOs ~~will~~ shall be considered official.

Should a provisionally certified State LEO meet the criteria specified by their action plan and EML, SECTION 3, their certification ~~will~~ shall be returned to full certification once they have successfully undergone their next State LEO check evaluation with the FDA/LPET.

Should a provisionally certified State LEO fail to meet the criteria specified in EML, SECTION 3 and/or follow the action plan, then their certification would be revoked.

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The procedures for revocation ~~must~~ shall follow SECTION V. QUALIFICATIONS AND CERTIFICATIONS, Part H. of the *Procedures* Document.

State LEOs who lose certification cannot be re-certified for a period of 60 days from the date of loss of certification. Recertification ~~will~~ shall require meeting the requirements for initial certification.

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SECTION 4: EQUIPMENT AND APPARATUS OF AID TO EVALUATION OFFICERS

While conducting ~~laboratory evaluations~~ on-site surveys, the ~~Federal~~ FDA/LPET or State LEO may find it extremely useful to have in his/her possession different types of equipment which ~~will~~ shall enable them to examine the apparatus in use and judge the proficiency of laboratory procedures in use for the examination of milk products. Some ~~evaluation officers~~ LEOs

currently use a large percentage of the equipment and apparatus listed below. Equipment should be maintained in proper working conditions to assure accuracy.

1. Brom thymol blue solution.
2. Chlorine test kit (chloramine or free chlorine).
3. Conductivity meter.
4. Anemometer.
5. Level (or cross test level).
6. Light meter (in foot-candles).
7. Maximum registering thermometer (MRT) for autoclaves.
8. Reference books (e.g., AOAC Official Methods of Analysis, Standard Methods for the Examination of Water and Wastewater).
9. Ruler, pocket - metric.
10. Special measuring flask (calibrated at 97-99-101-ml).
11. Taper gauge or drill bits for PLC loops.
12. Thermometer(s).
13. Weights - accurate (S/S1 or ASTM 1, 2 or 3).

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SECTION 5: GUIDELINES FOR CONDUCTING LABORATORY EVALUATIONS

The evaluations of laboratories by a ~~Federal~~ FDA/LPET or State LEO should be systematic. These guidelines are recommended to enable a complete ~~evaluation~~ survey of the laboratory facilities, equipment and records and of analyst technique.

Upon initial evaluation and/or renewal, the laboratory~~,~~ ~~must~~ shall make application for an evaluation upon a form provided by the ~~Federal~~ FDA/LPET or State LEO. The application ~~will~~ shall include the statement:

"I AGREE TO THE PROVISIONS OF THE NCIMS AND THE PROCEDURES FOR THE EVALUATION OF MILK LABORATORIES."

In preparation for the ~~laboratory evaluation~~ on-site survey, normally the laboratory director or supervisor should be notified in advance to insure the presence of analysts and the availability of samples for laboratory examination. In arranging for an initial ~~evaluation~~ on-site survey, laboratory officials should be told that all tests ~~must~~ shall be set up and that during the ~~evaluation~~ on-site survey the work of all analysts, who may perform any official methods ~~must~~ shall be observed. If ~~laboratory evaluation~~ on-site surveys are conducted on days when procedures, e.g. the SPC, are not normally performed, advance arrangements should be made to have samples on hand in order to observe the SPC procedure and the laboratory personnel should be requested to save countable plates from the previous day. Where the latter is not feasible, previously prepared and incubated plates may be brought to the laboratory by the ~~Federal~~ FDA/LPET or State LEO to permit observations of counting procedures.

On the designated ~~laboratory evaluation day~~ day of the on-site survey, delay arrival at the laboratory/facility until 10 - 15 minutes after the opening of the laboratory, to allow all personnel to start their day's activities normally. A visit to the laboratory director and/or supervisor's office should be made prior to entering the laboratory. At this time, the purpose of the ~~evaluation~~ on-site survey should be reviewed, and arrangements made to discuss the completed ~~laboratory evaluation~~ on-site survey informally with the laboratory director and/or supervisors on completion of the ~~evaluation~~ on-site survey . Assure that the ~~"Grade 'A'~~ Grade "A" Milk Laboratory Evaluation Request and Agreement Form" has been signed by a representative of the facility.

After entering the laboratory, the ~~Federal~~ FDA/LPET or State LEO should note the names of all analysts in the laboratory as/or after they are introduced and record the procedures performed by each.

Before beginning the on-site survey, the ~~Federal~~ FDA/LPET or State LEO should discuss the "ground rules" for the survey. Rules should be established for ~~procedural evaluations~~ the observation of the analysts' technique (e.g. whether an analyst can restart a procedure if the analyst notices that he/she make an error, how many times ~~may~~ an analyst may restart...).

During an ~~evaluation~~ on-site survey of a large laboratory, various analysts may be performing different examinations which may make a comprehensive ~~evaluation~~ survey difficult, particularly since all analysts are to be observed for each bacteriological and chemical procedure for which certification is requested. It is recommended that the ~~officer~~ FDA/LPET or State LEO establish a schedule so as to be in a position to evaluate apparatus and procedures used in the laboratory without disrupting, as far as

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possible, the routine examination of samples. Since it is expected that various portions of the evaluation forms ~~will~~ shall be used at separate times, it is advisable to note observed items of the various procedures on the left hand margins of the evaluation forms. By frequent referral to the noted items, the ~~Federal~~ FDA/LPET or State LEO ~~will~~ shall be reminded to observe all laboratory procedures in use and avoid misuse of the phrase "undetermined" (U) when procedures were actually in use but were not observed.

While observations of procedures are being made and the evaluation forms completed, certain precautions should be taken by the ~~Federal~~ FDA/LPET or State LEO:

1. Do not ask leading questions, e.g., do not ask analysts if plating media and dilution blanks are autoclaved at 120±1C for 15 minutes; simply ask how media and water blanks are autoclaved;

2. Try to keep the ~~evaluation on an~~ on-site survey informal ~~basis and~~ to minimize nervousness on the part of analysts, ~~e.g., do not over emphasize the evaluation of procedures by unusually close physical observation;~~ and

3. Stay alert during the observation of procedures so as to avoid necessary requests to repeat a technique overlooked during a procedure.

During the ~~evaluation~~ on-site survey it is probable that some items pertinent to receiving samples will not be observed. However, the ~~Federal~~ FDA/LPET or State LEO should determine from consultation with the laboratory supervisor the procedures used in receiving samples from the sample collectors:

1. Do the samples arrive at the laboratory as specified in the appropriate FDA-2400 Series Forms?

2. Are the samples suitably identified as to date, temperature and time of pickup, identification of sampler (e.g. name or initials) and sample identification or this information is readily available?

3. Is an extra sample or pilot container of appropriate size provided as a temperature control (TC)?

4. Are the raw milk sample containers no more than three-quarters (3/4) full?

5. Are samples ever rejected because they are outside of the acceptable temperature range at the time of pick-up from a sample storage depot or arrival at the laboratory, are samples ever rejected because they are too full or not properly identified?

6. How many hours pass (from initial time of collection of samples) before samples are plated?

Deviations are to be discussed with the analysts at some time after it has been observed and properly recorded. This discussion should include the nature of the deviation, any effect on

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the validity of the results, remedial action suggested and reasons justifying the change. All interested personnel should have an opportunity to look over the completed evaluation form and each major deviation should be discussed by the ~~officer~~ FDA/LPET or State LEO with interested staff. At that time comments should be invited from the staff concerning the ~~evaluation~~ survey. The ~~Federal~~ FDA/LPET or State LEO should make suggestions concerning any needed improvement of laboratory techniques. Following the discussion of procedures and competence of analysts, past split sample results of the laboratory should be discussed, suggestions made for improvement, and/or commendations made for superior performance.

In addition to a regularly scheduled visit, some ~~Federal~~ FDA/LPET or State LEOs find that an occasional unannounced visit to an accredited laboratory provides them with supporting information concerning laboratory practices. Information generated on all surveys (unannounced, scheduled, check on-site surveys) ~~must~~ shall be evaluated by the ~~Federal~~ FDA/LPET or State LEO and used to determine compliance with the NCIMS Milk Laboratory Program.

If at any time during an on-site survey there is interference with or willful refusal to permit the survey, the ~~Federal~~ FDA/LPET or State LEO ~~will~~ shall serve notice that the laboratory ~~will~~ shall not be certified or ~~will~~ shall be decertified until such time as the laboratory agrees to abide by the voluntary certification program. The laboratory may make reapplication by completing the application form and stipulating that future interference or refusals ~~will~~ shall result in non-certification or decertification for thirty days (30). Or, if at any time before or during any on-site survey the ~~Federal~~ FDA/LPET or State LEO feels their safety is in jeopardy or determines extensive non-compliance, they may terminate the survey. The ~~Federal~~ FDA/LPET or State LEO ~~must~~ shall indicate to the laboratory management ~~why~~ the reason the survey was terminated and ~~must~~ shall indicate what steps ~~must~~ shall be taken before a ~~resurvey~~ re-survey ~~will~~ shall be scheduled. The laboratory may make ~~reapplication~~ re-application by addressing the concerns that led to the termination of the survey and by completing the application form stipulating that the safety concerns and/or non compliance issues have been addressed.

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SECTION 6: LABORATORY EVALUATION REPORTS

EVALUATION FORMS

FDA-2400 Series Forms shall be completely identified with the name of the laboratory, the laboratory number, its location, date and the name of the individual making the evaluation when the option to send them with the narrative report is used. Forms pertaining to procedures not used should not be returned with the report.

Copies of the ~~survey~~ completed evaluation forms may be prepared for the laboratory evaluated. The ~~Federal~~ FDA/LPET or State LEO ~~must~~ shall maintain a complete copy of the on-site survey report, including forms. The laboratory/facility and ~~Federal~~ FDA/LPET or State LEO ~~must~~ shall maintain, at a minimum, copies of the last two (2) biennial/triennial survey~~s~~ reports, subject to verification by the State LEO and the FDA/LPET. In marking the official copies of the completed ~~survey~~ evaluation forms, leave items in compliance blank. When typing copies for transmittal to others, do not include check marks in the margin which were made at the time of the actual on-site survey for the convenience of the evaluating official.

NARRATIVE REPORT

The set of completed ~~survey~~ evaluation forms for the laboratory may accompany the narrative report which states the conclusions of the ~~Federal~~ FDA/LPET or State LEO as to whether or not the laboratory is doing acceptable work. If the completed evaluation forms do not accompany the narrative report, the report ~~must~~ shall be sufficiently detailed to allow readers to determine what is being cited without having to refer to the FDA-2400 Series Forms. Each form used shall have the revision date noted. Additional narrative reports, without FDA-2400 Series Forms, are to be sent to others that need to be informed as to the outcome of the laboratory ~~survey~~ evaluation. The copy of the narrative report submitted by email to the FDA/LPET ~~must~~ shall be accompanied by the appropriate, completed FDA summary template, both attached to the same

email. The State LEO ~~must~~ shall receive verification of receipt by return email and ~~must~~ shall maintain a copy of the verification in their records. The narrative report ~~must~~ shall identify the laboratory, give the laboratory number, show the date of the on-site survey, ~~who made the~~ name of the LEO that conducted the survey, list the prior status, list the date of the last on-site survey, indicate the present status, ~~what recommendations were made to correct any deviations,~~ what test(s) were approved, and ~~who was certified to do them~~ necessary changes to the IMS List.

Formats suitable for narrative reports appear on pages 29 - 36.

If choosing the option to send the narrative only via electronic submission, it ~~will~~ shall be necessary to summarize what each item is. Grouped under the title of each method observed (e.g., Standard Plate Count), list each major and/or minor deviation or omission numbered identically with the item number on the evaluation form and the corrective action necessary for compliance with standard procedures or good laboratory practices.

A paragraph headed "Remarks" or "Recommendations" may be included if the ~~officer~~ FDA/LPET or State LEO wishes to comment on an item, e.g., one which could be improved by a change in procedure or by new equipment, or for any comment which is not appropriately covered in other Sections of the report.

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After "Personnel and Procedures Certified" list the full name of all laboratory personnel qualified to make each individual test for which certification or approval is given. Include information on the analysts' last split sample performance. Also include a statement requiring participation in the Proficiency Testing Program to maintain certification (e.g., "To maintain certification, analysts ~~must~~ shall successfully participate in the Annual Proficiency Testing Program for all procedures for which certification has been granted").

Demonstrated proficiency or outstanding ability of individuals for one or more procedures which deserve special commendation may be given after the side heading "Commendations". If no commendation is warranted, delete this side heading from the narrative report. Such commendations should be used for outstanding performance.

Under "Conclusion" give a descriptive statement of the degree of acceptability or rejection of the procedures used by the laboratory, including recommendations for approval or rejection of the results of the laboratory. Some typical conclusions are given in the following text, and except in special circumstances, one of the conclusions listed ~~must~~ shall be used to indicate whether the results are (or are not) acceptable to State authorities for use in rating milk for interstate shipment, where this is the purpose of the evaluation.

CONCLUSIONS

1. This laboratory is accredited/approved as the procedures, records, facilities and equipment in use at the time of the on-site survey were in compliance with the requirements of the ~~*Grade 'A'*~~ *Grade "A" PMO.*

Explanation: Unqualified acceptance of the laboratory.

2. Although the procedures, records, facilities and/or equipment in use at the time of the ~~evaluation~~ on-site survey were in substantial compliance with the requirements of the ~~*Grade 'A'*~~ *Grade "A" PMO* the analyst/facility/equipment/records deviations noted ~~must~~ shall be corrected. This laboratory is accredited/approved for 30 - 60 days pending correction of the deviations and receipt of a letter by the ~~evaluation officer~~ FDA/LPET or State LEO detailing the corrections made. Upon receipt of such letter, full accreditation/approval ~~will~~ shall be given.

   Explanation: A qualified acceptance where the ~~Federal~~ FDA/LPET or State LEO believes that the deviations noted do not seriously affect the analytical results and that a letter explaining the corrective actions taken ~~will~~ shall be sufficient to ensure compliance.

3. Although the procedures, records, facilities and/or equipment in use at the time of the ~~evaluation~~ on-site survey did not substantially comply with the requirements of the ~~*Grade 'A'*~~ *Grade "A" PMO*, the analyst/facility/equipment/records deviations noted are readily correctable. This laboratory is accredited/approved for (___) days pending correction of the deviations. Corrections ~~must~~ shall be made and detailed in writing to the ~~evaluation officer~~ FDA/LPET or State LEO during this period. A new on-site survey ~~will~~ shall be scheduled upon receipt of the letter to assure full compliance.

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   Explanation: A qualified acceptance where procedural or technical errors or facilities which could have an effect on analytical results are noted but which are readily correctable by the analysts or management. Depending on the judgment of the FDA/LPET and State LEO, a period of ~~no~~ not more than ~~60~~ sixty (60) days usually is given to make the required adjustments before another survey is made or specified criteria are met, record, new equipment, etc. (some things may not require a return visit) to fully accredit (or approve) the laboratory.

4. This laboratory is not accredited/approved as the procedures, records, facilities and/or equipment in use at the time of the on-site survey did not comply with the requirements of the *Grade ~~'A' PMO"~~ "A" PMO*.

   Explanation: Severe deficiencies in facilities, records, staff and/or procedural techniques exist which would result in unacceptable results. A new on-site survey shall be made when the ~~Federal~~ FDA/LPET or State LEO has reason to believe that a rating would result in an acceptable rating. A new on-site survey would not be required for certified milk laboratories, CIS facility or screening facilities if the withdrawal was for facility deficiencies only. The laboratory, CIS facility or screening facility would be required to submit pictures, invoices, etc. to show compliance with the facility requirements noted in the last on-site ~~evaluation~~ survey.

FDA SUMMARY TEMPLATES

The narrative report sent to the FDA/LPET ~~must~~ shall be accompanied by the appropriate, completed FDA summary template for the laboratory, specifically representing the information required for verifying and updating the IMS List of accredited laboratories and CISs along with other useful information to be used by the FDA/LPET. Only the current revision of the FDA summary templates, authored by the FDA/LPET, may be used. ~~There are two FDA summary templates: one for full service laboratories and one for Appendix N Screening Only facilities (CIS and IS).~~ There is one (1) FDA summary template used by full service laboratories, and Appendix N and Screening Only facilities (CISs and ISs). The information captured on the FDA summary template ~~must~~ shall match the information provided in the narrative report (i.e., IMS number, facility identification, accreditation and certification status, dates, procedures, conclusion, etc.). The information captured may also lend itself to analyst/laboratory tracking and filing by the State LEO.

The appropriate FDA summary template form ~~must~~ shall also be used for the notification of changes in accreditation and certification status, and ~~must~~ shall be submitted by email to the FDA/LPET.

Directions for completing the FDA summary template, authored by LPET, ~~will~~ shall be updated with each revision of the FDA summary template, as necessary, and provided to the LEOs by email.

An example of a completed FDA summary template for each application appears on pages 37-40.

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REFERENCES

1. Copies of the FDA-2400 Series Forms can be obtained from the FDA/LPET ~~Federal~~ or State LEO(s).

   A list of the FDA/LPET ~~Federal~~ and State LEOs can be found at the website: http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/FederalStatePrograms/InterstateMilkShippersList/default.htm.

   Once at that website:

   For the FDA/LPET ~~Federal~~ LEOs click on the link ~~FDA CFSAN Personnel~~ "FDA CFSAN Personnel" and scroll down to the Laboratory Proficiency and Evaluation Team.

   For State LEOs click on the link ~~State Grade A Milk Regulatory, Rating and Laboratory Personnel~~ "State Grade A Milk Regulatory, Rating and Laboratory Personnel" and then click on your state. The table is organized by listing Regulatory personnel first, then Rating

personnel, and finally Laboratory personnel. Scroll down to the laboratory section to find the contact information for your state's LEO(s).

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TABLE 1: SPLIT SAMPLE COMPOSITION

PRODUCTS	NUMBER OF SAMPLES	DUPLICATES	ANALYSIS	NUMBER OF PRODUCT SAMPLES ANALYZED
HVD, or 2%, or Skim	3	1	Plate Count /Coliforms	3
			Phosphatase	1
			Vitamins	3
Cream, heavy	2	1	Plate Count /Coliforms	2
			Phosphatase	2
			Vitamins	2
Cream, light	2[a]	0 or 1	Plate Count /Coliforms	1
			Phosphatase	2[b]
			Vitamins	1
Chocolate	2	1	Plate Count /Coliforms	2
			Phosphatase	1
			Vitamins	2
Raw	6	3	Plate Count	6
Raw	8	4	Inhibitors	8
			Somatic Cells	8
			Added Water[c]	8
Dairy Water	8	4	Coliforms	8
			Heterotrophic Plate Count	8
Milk Totals	23[a]	10 or 11	Plate Count	14
			Coliforms	8
			Phosphatase	6
			Vitamins	8
			Inhibitors	8
			Somatic Cells	8
			Added Water[c]	8
Dairy Water Total	8	4	Coliforms	8
			Heterotrophic Plate Count	8

a - One of these samples serves as the temperature control (TC).
b - These two (2) samples are tested for both residual and reactivated phosphatase
c - This analysis is optional.

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TABLE 2: STATISTICAL LIMITS

TEST	REJECTION LIMIT 1 (L_1)*	REJECTION LIMIT 2 (L_2)*
Plate Counts	0.268	0.179
Direct Somatic Cell Count	0.300	0.200
Electronic Somatic Cell Count	0.212	0.143
Vitamins	0.300	0.200
Electronic Phosphatase Count	0.300	0.200
Dairy water MPN	0.949	0.632
Heterotrophic Plate Count	0.300	0.200

* To be used with logarithmic mean.

TABLE 3: MAXIMUM NUMBER OF UNACCEPTABLE RESULTS

NUMBER OF RESULTS PER TEST (N)	MAXIMUM NUMBER OF UNACCEPTABLE RESULTS PER TEST FOR APPROVAL
5 – 10	1
11 – 20	2
21 – 30	3

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EXAMPLE REPORT #1

Report of a Biennial On-Site Evaluation

of

City Health Department Milk Laboratory

Accredited Laboratory
NCIMS LAB #####

100 South Main Street
City, State 78000

On

March 1, 2010

By

LEO Name
Laboratory Evaluation Officer
State Department of [Health, Agriculture}
100 Healthy Way
City, State 78000

Last Full Evaluation Date: March 19, 2008
Next Evaluation Due By: March 31, 2012

A copy of the "Grade "A" Grade 'A' Milk Laboratory Evaluation Request and Agreement Form" is signed and is on file.

Previous Laboratory Status: Fully certified for [5, 9C13, 9C14, 9D3, 12, 20, 22, 24, 28]

Present Laboratory Status: Fully certified for [5, 9C13, 9D3, 12, 16, 20 22, 24, 28] pending receipt within 60 days of correction of deviations resulting from on - site evaluation of March 1, 2010.

Other changes that need to be made to IMS list, etc: Update Anniversary Date, drop procedure 9C14, add procedure 16.

The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the *Grade "A" Grade 'A' PMO*. If forms accompany the narrative then deviated items are marked with an "X" on the evaluation forms. Items marked "U" are

ures and/or

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procedures equipment marked "O" are not used. Items marked "NA" are optional procedural techniques and/or equipment not applicable to designated laboratory procedures. Repeat deviations are marked by an asterisk "*". Noted items are not considered deviations. The phrase "Note" as used in these narrative reports is to suggest or remark upon items which would improve laboratory functions. These are usually considered to be good laboratory practices but are not listed in the FDA-2400 Series Forms and are not debitable items.

DEVIATIONS AND CORRECTIVE ACTIONS

ITEM METHOD

CULTURAL PROCEDURES – GENERAL REQUIREMENTS (rev. 2/10)

2. Records

2e Corrections to all records follow appropriate requirements

During the review of the autoclave records it was noticed that there were a number a items written over.

Analysts are to be reminded of the proper protocol for correcting mistakes. Cross out the error with one line, initial, date and write the correct information next to it.

Send copies of the March and April autoclave records.

3. Thermometers

3a NIST Thermometer

#NOTE: The graduations on the lower end of the NIST thermometer are so worn that it is difficult to read. It is suggested that a new thermometer be purchased.

The other option is to use the new NIST traceable unit that is available for use in the rest of the laboratory.

3c3 No tag was found on the freezer thermometer

Although the accuracy check was documented the unit was not tagged.

Tag the thermometer with the following: identification/location, date of check, temperature checked and the correction factor.

Send a copy of the tag.

5. Freezer

5b Maintains -15C or below

Over the past four months at least 50% of the days noted with the unit out of temperature range with no corrective action noted.

- This is a serious violation and no controls or samples may be kept in the unit until it is proven that that the unit holds the proper temperature.
- Send copies of the freezer temperature records for the next 4 months. If the unit cannot be maintained then a new one shall will need to be purchased.

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13. Autoclave

- *13i Performance check*
- There were no thermometers for the incubation units for the spore check. There shall must be a way to check the appropriate temperature range for the test.
- Please purchase thermometers for these units and send a copy of the purchase order, the temperature calibrations when received and the temperature records for the two months following.

TECHNIQUES

PETRIFILM AEROBIC AND COLIFORM COUNTS (IMS# 5,20 rev. 1/09)

No deviations noted. The analysts showed marked improvement over the last biennial on-site.

PASTEURIZED MILK CONTAINERS (IMS# 22 rev. 1/09)

10. Collection of Surface Rinse Samples

- *10b2 While adding the rinse solution to the container, do not touch the bottle of rinse solution to the container.*
- One analyst held the bottle against the container while adding the rinse solution.
- Use aseptic technique when adding the rinse solution.

DELVOTEST P 5 PACK (IMS# 9D3 rev. 2/10)

No deviations noted.

DMSCC (IMS# 12 rev. 2/10)

21. Sample Measurement

- *21c Touch the slide with the tip and expel the test portion.*
- One analyst held the syringe above the slide and dripped the milk.
- Take the syringe and hold it vertically against the slide, depress the plunger slowly allowing the milk to be expelled. Then touch off to a dry spot.

ESCC – BENTLEY 150 (IMS# 16 rev. 10/07)

No deviations noted.

FLUOROPHOS ALP (IMS# 28 rev. 6/05)

15. Instrument and Reagent Checks

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15g2b Reconstituted Substrate / Buffer Stability Check A/D Value Recorded
The A/D value for this check was missing on several days of testing records during the period evaluated. While this may be from having to reconstitute a new bottle of substrate because the A/D value was greater than 1200, the corrective action shall must be noted with both the old *AND* new values recorded.

DAIRY WATERS (IMS# 24 rev. 1/09)

No deviations noted.

CHARM SL BETA LACTAM (IMS# 9C13 rev. 1/10)

No deviations noted.

PERSONNEL & PROCEDURES OBSERVED

Analyst	5	9C13	9D3	12	16	20	22	24	28	ON-SITE Last 2	SPLITS Last 2
Analyst 1	X	X	X	X	X	X	X	X	X	3/10, 3/08	10/09, 10/08
Analyst 2	X	X	X	X	X	X	X	X	X	3/10, 3/08	10/09, 10/08
Analyst 3	X	X	X	X	X	X	X	X	X	3/10, 3/08	10/09, 10/08
Analyst 4	X	X	X	X		X	X	X	X	3/10	10/09
Analyst 5*	X	X	X	X	X	X	X	X	X	3/08, 3/06	10/09, 10/08

X = Fully Certified
* = Analyst excused – on medical leave.
5 = Petrifilm Aerobic Count
9C13 = Charm SL Beta Lactam
9D3 = Delvotest 5 Pack
12 = DMSCC
16 = ESCC (Bentley 150)
20 = Petrifilm Coliform Count
22 = Pasteurized Milk Containers
24 = Dairy Waters
28 = Advanced Fluorometer

CONCLUSION

~~Although the procedures, records, facilities and equipment in use at the time of the evaluation were in substantial compliance with the requirements of the *Grade "A"* *Grade 'A' PMO* the analyst, equipment and record deviations noted shall must be corrected. This laboratory is accredited until May 1, 2010 pending correction of the deviations and receipt of a letter by the evaluation officer detailing the corrections made. Upon receipt of such letter, full accreditation shall will be given.~~

~~Sincerely,~~
~~LEO~~

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~~EXAMPLE REPORT #2~~

~~REPORT Of an Biennial On-Site/~~
~~Supplemental (analyst, procedure, walk-through)/~~
~~Unofficial/Check~~

~~Certified Laboratory~~
~~NCIMS Lab #####~~

~~Certified Industry Supervisor~~
~~CIS #####~~

~~Appendix N Screening Site~~

~~NAME OF SITE~~
~~Address~~
~~Date of Evaluation~~
~~By LEO's name~~

~~Previous Laboratory Status: Fully/provisionally/conditionally Certified until [date]~~
~~Previous Procedures: X, X, X~~

~~Present Laboratory Status: Fully/provisionally/conditionally Certified until [date], pending acceptable response to this report~~
~~Procedures evaluated: X, X~~

~~A copy of the "Grade 'A' Milk Laboratory Evaluation Request and Agreement Form" is signed and is on file with LEO.~~

~~Other changes that need to be made to IMS list, etc: None or addition of analysts, change in procedures, etc.~~

~~The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade "A" Grade 'A' PMO. If forms accompany the narrative then deviated items are marked with an "X" on the evaluation forms. Items marked "U" are undetermined because of local conditions at the time of the evaluation. Laboratory procedures and/or equipment marked "O" are not used. Items marked "NA" are optional procedural techniques and/or equipment not applicable to designated laboratory procedures. Repeat deviations are marked by an asterisk "*". Noted items are not considered deviations. The phrase "Note" as used in these narrative reports is to suggest or remark upon items which would improve laboratory functions. These are usually considered to be good laboratory practices but are not listed in the FDA 2400 Series Forms and are not debitable items.~~

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DEVIATIONS AND CORRECTIVE ACTIONS

ITEM METHOD

CULTURAL PROCEDURES FOR CERTIFIED LAB [rev. 2/10] /
GENERAL REQUIREMENTS FOR APPENDIX N [rev. 2/10]

CERTIFIED LAB

3. Thermometers

3c2 All test temperature measuring devices are checked at temperature of use.
The thermometers in the media section were checked for accuracy but were not always done at the temperature of use as required. The hot air oven was checked at 65C vs. 170C.
Re-check the thermometer and send with the response.

3c3a Tags include correction factors on temperature measuring devices.
The tags did not include correction factors in media area.
Send copies of the tags.

APPENDIX N LAB

1c Adequate lighting, [NCIMS Certified Laboratories, and Certified Industry Supervisors >50 foot candles at the working surface (pref. 100)].

During the technique demonstration, the wall light was not used. The lighting measured 14-24 foot candles in the confirmation testing area. The confirmation testing area had 83-105 foot candles when the wall light was utilized. Whenever testing is being conducted the wall light shall must be utilized.

It was determined during the survey that the screening test area had 20-25 foot candles of light. Add additional lighting to the area to increase to >50 ft-candles and send verification.

TESTS-LIST ALL TESTS OBSERVED and DEVIATIONS OF TECHNIQUES.

CERTIFIED LAB

Standard Plate Count, Coliform, and Simplified Count Methods (IMS#2 rev. 1/09)

5. Sample Agitation

5b1 Shake samples raw samples 25 times in 7 sec with 1 ft movement
All analysts did not shake quickly enough. Raw samples need to be shaken more vigorously.

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5b2 Invert filled retail container 25 times, each inversion a complete down and up motion
All analysts did not complete the inversions.

6d Avoid foam if possible when pipet is inserted into sample.
All analysts did not avoid the foam. The raw milk container may be tapped on the container on counter and tilted as to show clear spot on surface of milk. The pipet is not inserted more than 2.5 cm. Analysts may use the cap of retail containers or sterile Petri dish to adjust the pipet volume and not adjust pipet volume while pipet is still in liquid portion of sample.

APPENDIX N LAB

CHARM SL BETA LACTAM (IMS# 9C13 rev 2/10)

3a1 Incubator level. Temperature checked daily (day of use), records maintained.
The temperature is not being recorded to the tenth of a degree.
Please instruct analysts to record the strip incubator to the tenth of a degree.
Send copies of the temperature record for the next two months.

14d Reader tapes or computer printouts maintained for two years.
It would be best to keep the printouts with the daily sheets as it is more difficult to look through separate stacks to match the tankers tested.

Comments/Recommendations: Optional Areas that may need to be addressed or LEO has some concern.

PERSONNEL AND PROCEDURES CERTIFIED

LEO IS TO LIST ALL THE PERSONNEL AND PROCEDURES THAT WERE EVALUATED AT THIS AUDIT. INCLUDE A LETTER (X, C, N, ETC.) THAT DENOTES THE STATUS OF ANALYSTS (REFERENCED AS BELOW) ON THE EVALUATION AND SPLIT SAMPLES.

CERTIFIED LAB

PERSONNEL AND PROCEDURES CERTIFIED

	SPC/PACCOLI/PCCPMC	D3	I1	C[3,9,10,12]	DMSCC	PHOS[28]		
Name Analyst 1	X/N	X/X	X	C	X	X	X	X
Name Analyst 2	X/P	X/X	X	X	X	X	X	X

[X denotes full certification in the indicated procedures pending acceptable performance in the annual proficiency testing program (split sample) for all procedures for which certification has been granted. P denotes provisional certification pending acceptable performance in the annual

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~~Date~~

~~proficiency testing program for all procedures for which certification has been granted. C denotes conditional certification pending acceptable performance in the annual proficiency testing program for all procedures for which certification has been granted. N denotes no certification status granted.].~~

~~APPENDIX N LAB~~

~~Certified Industry Analysts~~	~~2010 On-Site Evaluation TEST KIT~~	~~4/2010 Split Sample Survey TEST KIT~~
~~Name CIS 1~~	~~x (CIS)~~	~~x~~
~~Name CIS 2~~	~~x (CIS)~~	~~x~~
~~Name CIS 3~~	~~No Longer Employed~~	~~x~~

~~Industry Analysts~~	~~2010 On-Site Evaluation TEST KIT~~	~~6/2010 Split Sample Survey TEST KIT~~
~~Name IA 1~~	~~x~~	~~x~~
~~Name IA 2~~	~~x~~	~~x~~

~~CONCLUSION~~

~~Use the proper conclusion found on pages 24 & 25.~~

EXAMPLE REPORT #1

Report of a Biennial On-Site Evaluation of
{*Laboratory Name*}
{*Address of Physical Location*}
{*City, State & Zip Code*}

IMS LAB # {*SSXXX or SSXXXX*}

On

{*Date of Survey (Month Day(s), Year)*}

By

{*Name of LEO*}
Laboratory Evaluation Officer
State Department of {*Health or Agriculture*}
{*Physical / Mailing Address*}
{*City, State & Zip Code*}

Date of Last Evaluation: {*Month Day(s), Year*}
Prior Procedures (IMS Code): 5, 9C13, 9C14, 9D3, 12, 20, 22, 24, 28
Prior Laboratory Status: Fully Accredited

Evaluated Procedures: 5, 9C13, 9D3, 12, 16, 20 22, 24, 28
Present Laboratory Status: Fully Accredited, pending receipt of a satisfactory written response to the noted deviations on or before {*Month Day(s), Year - specified date usually 60 days from expected receipt of the narrative report*}.

Changes to IMS List: Drop procedure 9C14, add procedure 16.

A copy of the Grade "A" Milk Laboratory Evaluation Request and Agreement Form is signed and on file.

The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade "A" Pasteurized Milk Ordinance. If FDA 2400 series forms accompany the narrative report, deviated items are marked with an "X"; undetermined items because of local conditions at the time of the evaluation are marked "U"; on the accompanying evaluation forms. laboratory procedures and/or equipment not used are marked "O"; optional procedural techniques and/or equipment not applicable to designated laboratory procedures are marked "NA"; repeat deviations from the previous on-site survey are marked with an asterisk "*"; and supplementary information or suggested good laboratory practices not specifically listed in the FDA 2400 series forms or considered stand-alone deviations but are intended to improve laboratory function are designated by "Note" and do not require a written response.

DEVIATIONS AND CORRECTIVE ACTIONS:

Item	**Method**
	{Cite procedure title and revision date for each FDA 2400 series form used to conduct the survey followed by any applicable deviations, notes or relevant remarks/comments}
{Item}	*{First statement should be a concise descriptive representation of the observed issue with specific example(s) of occurrence(s) in one or two sentences}* {Second statement should specifically describe what, how and/or when the lab is to remedy the issue} {The third statement should specifically describe what is to be submitted by the lab along with the written response (copies of new or revised records, service manifest, new purchase shipping manifest, certificate of authenticity, etc.) to the LEO as verification that appropriate corrective action was taken, when applicable}.
	Cultural Procedures – General Requirements (rev. 2/10)
2e	During the review of the autoclave records it was noted that there were several data points written over. Analysts are to use proper protocol for correcting mistakes: cross out the error with a single line, initial and write the correct information next to it. Note that the date discovered/corrected should also be documented as a good laboratory practice. Lab is to send copies of the autoclave records from the time of the survey that demonstrate proper corrective action being taken.
3a	Note: The graduations on the lower end of the NIST thermometer are so worn that it is difficult to read. If the graduations cannot be restored, it is suggested that a new thermometer be purchased. Optionally, the lab may use the new electronic/digital NIST traceable temperature measuring device (with access to certificate of accuracy and annual ice point check records) that is available for use in the rest of the laboratory.
3c3	Although the accuracy check was documented, no tag was found on the freezer thermometer. Tag the thermometer with the following information: identification or serial number (SN) / location, date of check, temperature checked and the correction factor. Send a copy of the new tag.
5b	Over the past four months at least 50% of the days observed in the temperature monitoring records showed that the freezer was consistently greater than the acceptable temperature range with no corrective action documented. This is a serious violation and no reagents or controls may be kept in this freezer until it is proven that that the freezer holds the temperature within the acceptable temperature range (< -15.0 ºC). If this freezer cannot maintain the proper temperature, then a new freezer will need to be purchased. Send copies of the repaired or new freezer temperature monitoring records for the next 4 months from the date of the survey.

13i There were no accuracy-checked thermometers for the spore incubation units used for the autoclave performance check. There must be a way to check the appropriate temperature range for the test. Lab must obtain/purchase thermometers dedicated for these units. Send a copy of the shipping manifest (if newly purchased), the accuracy check records and the temperature monitoring records for the following two months.

Petrifilm Aerobic and Coliform Counts (5 &20, rev. 1/09)

No deviations were noted.

Comment: The analysts showed marked improvement over the last biennial on-site survey.

Pasteurized Milk Containers (22, rev. 1/09)

10b2 One analyst held the bottle against the container while adding the rinse solution. Use aseptic technique while adding the rinse solution to the container, and do not touch the bottle while pouring the rinse solution to the container.

Appendix N – General Requirements (rev. 2/10)

1-8 See Cultural Procedures, items 1-32 (as applicable).

9 See Cultural Procedures, item 33 (as applicable).

10a Note: Suitability on new purchased lot of test kits should be conducted in a timely manner that allows enough time to replace the new lot of test kits upon failure and prior to running out of previous lot in use.

12 The lab records showed that a new bulk milk tanker sample was collected without a documented explanation to perform confirmation testing of a presumptive positive load. A resample may only be collected at the discretion of the State regulatory agency and with appropriate justification and documentation.

14 See Cultural Procedures, item 34 (as applicable).

15 See Cultural Procedures, items 35 (as applicable).

Delvotest P 5 Pack (9D3, rev. 2/10)

No deviations were noted.

Charm SL Beta-Lactam Test (IMS# 9C13 rev. 1/10)

4c1 Commingled raw milk was being collected from a raw milk silo for preparation of the Negative and subsequent Positive Controls without prior testing for the presence of drug residues. Silo milk must be shown to test negative using the test kit of use prior to preparing the controls for use or storage (previously tested negative). Send copy of records demonstrating that previously tested negative raw milk is used to prepare the Negative and Positive Controls.

Direct Microscopic Somatic Cell Count (12 rev. 2/10)

21e When preparing the milk smears, one analyst held the metal (positive displacement) syringe above the slide and dripped the milk sample test portion. Holding the syringe almost vertically and the syringe tip contacting the slide near the center of the delineated area for the milk smear gently depress the plunger to slowly expel the milk. Maintaining the plunger fully depressed, remove the tip from the milk and touch off to a dry spot.

Electronic Somatic Cell Count – Bentley 150 (16, rev. 10/07)

No deviations were noted.

Dairy Waters using Multiple Tube Fermentation (MTF) Technique by Most Probable Number (MPN), Heterotrophic Plate Count (HPC) and Idexx Colilert-24 by Presence-Absence (24, rev. 1/09)

No deviations noted.

Alkaline Phosphatase Test – Advanced Instruments Fluorophos (28 rev. 6/05)

15g2b The A/D value for substrate / buffer stability as part of the Daily Performance Check was missing on several days of official sample testing records reviewed during the survey period. While this may be from having to reconstitute a new bottle of substrate because the A/D value was greater than 1200, the corrective action must be documented with both the old and new values recorded.

PERSONNEL & PROCEDURES CERTIFIED:

Analyst	Procedures (IMS Codes)									**ON-SITE Last 2**	**SPLITS Last 2**
	5	9C13	9D3	12	16	20	22	24	28		
Analyst 1	F	F	F	F	F	F	F	F	F	m/yy, m/yy	m/yy, m/yy
Analyst 2	F	F	F	F	F	F	F	F	F	m/yy, m/yy	m/yy, m/yy
Analyst 3	F	F	F			F	F	F	F	m/yy, m/yy	m/yy, m/yy
Analyst 4	F	F	F			F	F	F	F	m/yy	m/yy
Analyst 5*	F	F	F	F	F	F	F	F	F	m/yy, m/yy	m/yy, m/yy

F = Fully Certified
P = Provisionally Certified
C = Conditionally Certified
N = Not Certified
* = Analyst excused – on medical leave.

To maintain certification, analysts must successfully participate in the Annual Proficiency Testing Program for all procedures for which certification has been granted.

CONCLUSION:

Although the procedures, records and/or equipment in use at the time of the evaluation were in substantial compliance with the requirements of the Grade "A" Pasteurized Milk Ordinance, the analyst/facility deviations noted must be corrected. This laboratory is accredited, pending correction of the deviations and receipt of a letter detailing the corrections made. Upon receipt of a satisfactory written response and other appropriate documentation detailing the corrective actions taken on or before {***Month Day(s), Year*** *- specified date usually 60 days from expected receipt of the narrative report*}, full accreditation status will be granted.

EXAMPLE REPORT #2

Report of a Supplemental {used for interim accreditation of *new analyst(s), new procedure(s), check surveys or walk-through*} On-Site Evaluation of

{*Laboratory Name*}
{*Address of Physical Location*}
{*City, State & Zip Code*}

IMS LAB # { *SSXXX or SSXXXX* }

On

{*Date of Survey (Month Day(s), Year)*}

By

{*Name of LEO*}
Laboratory Evaluation Officer
State Department of {*Health or Agriculture*}
{*Physical / Mailing Address*}
{*City, State & Zip Code*}

Date of Last Evaluation: {*Month Day(s), Year*}
Prior Procedures (IMS Code): 5, 9C13, 9C14, 9D3, 12, 20, 22, 24, 28
Prior Laboratory Status: Fully Accredited

Evaluated Procedure: 12 and 16
Participating Analysts: Analyst 3 and Analyst 4
Present Laboratory Status: Fully Accredited, pending receipt of a satisfactory written response to the noted deviations on or before {*Month Day(s), Year - specified date usually 60 days from expected receipt of the narrative report*}.

Changes to IMS List: None.

A copy of the Grade "A" Milk Laboratory Evaluation Request and Agreement Form is signed and on file.

The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade "A" Pasteurized Milk Ordinance. If FDA 2400 series forms accompany the narrative report, deviated items are marked with an "X"; undetermined items because of local conditions at the time of the evaluation are marked "U"; on the accompanying evaluation forms. laboratory procedures and/or equipment not used are marked "O"; optional procedural techniques and/or equipment not applicable to designated laboratory procedures are marked "NA"; repeat deviations from the previous on-site survey are marked with an asterisk "*"; and supplementary information or suggested good laboratory practices not specifically listed in the FDA 2400 series forms or considered stand-alone deviations but are intended to improve laboratory function are designated by "Note" and do not require a written response.

DEVIATIONS AND CORRECTIVE ACTIONS:

Item	Method
	Cultural Procedures – General Requirements (rev. 2/10)
3	The thermometer used in the water bath dedicated for the Electronic Somatic Cell Count procedure was not labeled. Records for this thermometer's accuracy check were current. The thermometer label was replaced during the survey. No further corrective action is required.
20	See ESCC item 4a below.
	Direct Microscopic Somatic Cell Count
25i	Monthly comparison counts were not being evaluated properly. When 3 or more analysts are participating, the RpSm method of evaluation must be used (see PAC item 17a1). Submit copies of the monthly comparison counts from the date of this on-site survey showing the use of the RpSm method of evaluation. No technique deviations were observed.
	Electronic Somatic Cell Count – Bentley 150 (16, rev.)
4a	The water in the ESCC water bath was not circulating. Lab must repair or replace the circulating water pump before the water bath can be used to warm the ESCC samples immediately prior to analysis. Submit itemized service receipt or shipping manifest along with written response. No technique deviations were observed.

PERSONNEL & PROCEDURES CERTIFIED:

Analyst	Procedures (IMS Codes)									**ON-SITE Last 2**	**SPLITS Last 2**
	5	9C13	9D3	12	16	20	22	24	28		
Analyst 1	F	F	F	F	F	F	F	F	F	m/yy, m/yy	m/yy, m/yy
Analyst 2	F	F	F	F	F	F	F	F	F	m/yy, m/yy	m/yy, m/yy
Analyst 3	F	F	F	C	C*	F	F	F	F	m/yy, m/yy	m/yy, m/yy
Analyst 4	F	F	F	C	C*	F	F	F	F	m/yy	m/yy
Analyst 5	F	F	F	F	F	F	F	F	F	m/yy, m/yy	m/yy, m/yy

F = Fully Certified
P = Provisionally Certified
C = Conditionally Certified
N = Not Certified
E = Analyst excused – on medical leave.

* Conditional certification status was granted at the end of the on-site survey because the comparison study was submitted on {*Month Day, Year*} and found to be satisfactory as of {*Month Day, Year*}, and are on file.

To maintain certification, analysts must successfully participate in the Annual Proficiency Testing Program for all procedures for which certification has been granted.

CONCLUSION:

Although the procedures, records and/or equipment in use at the time of the evaluation were in substantial compliance with the requirements of the Grade "A" Pasteurized Milk Ordinance, the analyst/facility deviations noted must be corrected. This laboratory is accredited, pending correction of the deviations and receipt of a letter detailing the corrections made. Upon receipt of a satisfactory written response and other appropriate documentation detailing the corrective actions taken on or before {***Month Day(s), Year*** *- specified date usually 60 days from expected receipt of the narrative report*}, full accreditation status will be granted.

EXAMPLE REPORT #3

Report of a Supplemental On-Site Evaluation of
an Appendix N Bulk Milk Tanker Screening Facility at

{Laboratory Name}
{Address of Physical Location}
{City, State & Zip Code}

IMS LAB # *{SS6xx}*

On

{Date of Survey (Month Day(s), Year)}

By
{Name of LEO}
Laboratory Evaluation Officer
State Department of *{Health or Agriculture}*
{Physical / Mailing Address}
{City, State & Zip Code}

Date of Last Evaluation: *{Month Day(s), Year}*
Prior Procedures (IMS Code): 9C14
Prior Laboratory Status: Fully Accredited

Evaluated Procedures: 9C15
Participating Analysts: Analyst 1 and Analyst 2
Present Laboratory Status: Fully Accredited, pending receipt of a satisfactory written response to the noted deviations on or before *{Month Day(s), Year - specified date usually 60 days from expected receipt of the narrative report}*.

Changes to IMS List: Drop procedure 9C14 and add procedure 9C15.

A copy of the Grade "A" Milk Laboratory Evaluation Request and Agreement Form is signed and on file.

The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade "A" Pasteurized Milk Ordinance. If FDA 2400 series forms accompany the narrative report, deviated items are marked with an "X"; undetermined items because of local conditions at the time of the evaluation are marked "U"; on the accompanying evaluation forms. laboratory procedures and/or equipment not used are marked "O"; optional procedural techniques and/or equipment not applicable to designated laboratory procedures are marked "NA"; repeat deviations from the previous on-site survey are marked with an asterisk "*"; and supplementary information or suggested good laboratory practices not specifically listed in the FDA 2400 series forms or considered stand-alone deviations but are intended to improve laboratory function are designated by "Note" and do not require a written response.

DEVIATIONS AND CORRECTIVE ACTIONS:

Item	Method
	Appendix N – General Requirements (rev. 2/10)
1c	During survey of analyst technique, the previously dedicated wall light was not used. The lighting measured 14-24 foot candles in the testing area, which was below the requirement of > 50 foot-candles at the working surface. The testing area had 83-105 foot candles when the wall light was utilized. Whenever testing is being conducted the wall light must be utilized.
3c3a	The tags for those temperature measuring devices in the media preparation area did not include correction factors. These tags are to include the correction factor determine at the temperature of use. Send copies of the revised tags.
	Charm 3 SL3 Beta-Lactam Test (9C15, rev. 11/12)
5b1	Two analysts shook samples 25 times, but always took greater than 7 sec. Analysts are to shake raw milk samples 25 times in 7 sec with 1 ft movement.

PERSONNEL & PROCEDURES CERTIFIED:

		− Procedures (IMS Codes) −		Last 2	Last 2
Analyst	Position	9C[14*]	9C[15]	Surveys	Splits
Analyst 1	CIS	N[1]	C	m/yy, m/yy	m/yy, m/yy
Analyst 2	CIS	N[1]	C	m/yy, m/yy	m/yy, m/yy
Analyst 3	IA	NA[2]		m/yy, m/yy	m/yy, m/yy
Analyst 4	IA	NA[2]		m/yy, m/yy	m/yy, m/yy

F	=	Fully Certified
FA	=	Fully Approved
P	=	Provisionally Certified
PA	=	Provisionally Approved
C	=	Conditionally Certified
CA	=	Conditionally Approved
N	=	Not Certified
NA	=	Not Approved

1 Laboratory accreditation, and as a consequence analyst certification has been removed due to voluntary withdraw during this on-site survey for the indicated procedure.
2 Approval status was removed due to analyst no longer employed.

To maintain approve status, analysts must successfully participate in annual milk split sample performance evaluation provided by the Industry Supervisor or a State Laboratory Evaluation Officer for all procedures for which approval has been granted.

CONCLUSION:

Although the procedures, records and/or equipment in use at the time of the evaluation were in substantial compliance with the requirements of the Grade "A" Pasteurized Milk Ordinance, the analyst/facility deviations noted must be corrected. This laboratory is approved, pending correction of the deviations and receipt of a letter detailing the corrections made. Upon receipt of a satisfactory written response and other appropriate documentation detailing the corrective actions taken on or before {***Month Day(s), Year*** *- specified date usually 60 days from expected receipt of the narrative report*}, fully accreditation status will be granted.

EXAMPLE REPORT #4

Report of a Biennial On-Site Evaluation of
an Appendix N Bulk Milk Tanker Screening Only Facility at

{*Laboratory Name*}
{*Address of Physical Location*}
{*City, State & Zip Code*}

IMS LAB # {*SS999-yyyy*}

On

{*Date of Survey (Month Day(s), Year)*}

By

{*Name of LEO*}
Laboratory Evaluation Officer
State Department of {*Health or Agriculture*}
{*Physical / Mailing Address*}
{*City, State & Zip Code*}

Date of Last Evaluation: {*Month Day(s), Year*}
Prior Procedures (IMS Code): 9I1
Prior Laboratory Status: Fully Approved

Evaluated Procedures: 9I1
Present Laboratory Status: Fully Approved, pending receipt of a satisfactory written response to the noted deviations on or before {*Month Day(s), Year - specified date usually 60 days from expected receipt of the narrative report*}.

A copy of the Grade "A" Milk Laboratory Evaluation Request and Agreement Form is signed and on file.

The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade "A" Pasteurized Milk Ordinance. If FDA 2400 series forms accompany the narrative report, deviated items are marked with an "X"; undetermined items because of local conditions at the time of the evaluation are marked "U"; on the accompanying evaluation forms. laboratory procedures and/or equipment not used are marked "O"; optional procedural techniques and/or equipment not applicable to designated laboratory procedures are marked "NA"; repeat deviations from the previous on-site survey are marked with an asterisk "*"; and supplementary information or suggested good laboratory practices not specifically listed in the FDA 2400 series forms or considered stand-alone deviations but are intended to improve laboratory function are designated by "Note" and do not require a written response.

DEVIATIONS AND CORRECTIVE ACTIONS:

Item	Method
	Appendix N – General Requirements (rev. 2/10)
1c	Note: During the survey of analyst technique, the lighting in the immediate testing area measured 20-25 foot candles. Additional lighting should be added to the testing area, increasing the lighting to be >50 foot-candles. Whenever testing is being conducted the additional lighting should be utilized.
3	Digital thermometer placed in well of heat block fit loosely. Probe/sensor of digital/electronic temperature measuring device must have proper diameter to fit snugly into heat block or it must be placed in tube with water and placed in test well.
	Idexx New Snap Beta-Lactam Test (9I1, rev. 7/12)
6c	The sample and control tubes were not labeled during observation of the analysts' testing technique. All tubes and devices must be properly labeled for testing regardless of how many samples are being tested.

PERSONNEL & PROCEDURES APPROVED:

	− Procedures (IMS Codes) −	Last 2	Last 2
Analyst	9I[1]	Surveys	Splits
Analyst 1	FA	m/yy, m/yy	m/yy, m/yy
Analyst 2	FA	m/yy, m/yy	m/yy, m/yy
Analyst 3	FA	m/yy, m/yy	m/yy, m/yy
Analyst 4	FA	m/yy, m/yy	m/yy, m/yy

FA = Fully Approved
PA = Provisionally Approved
CA = Conditionally Approved
NA = Not Approved

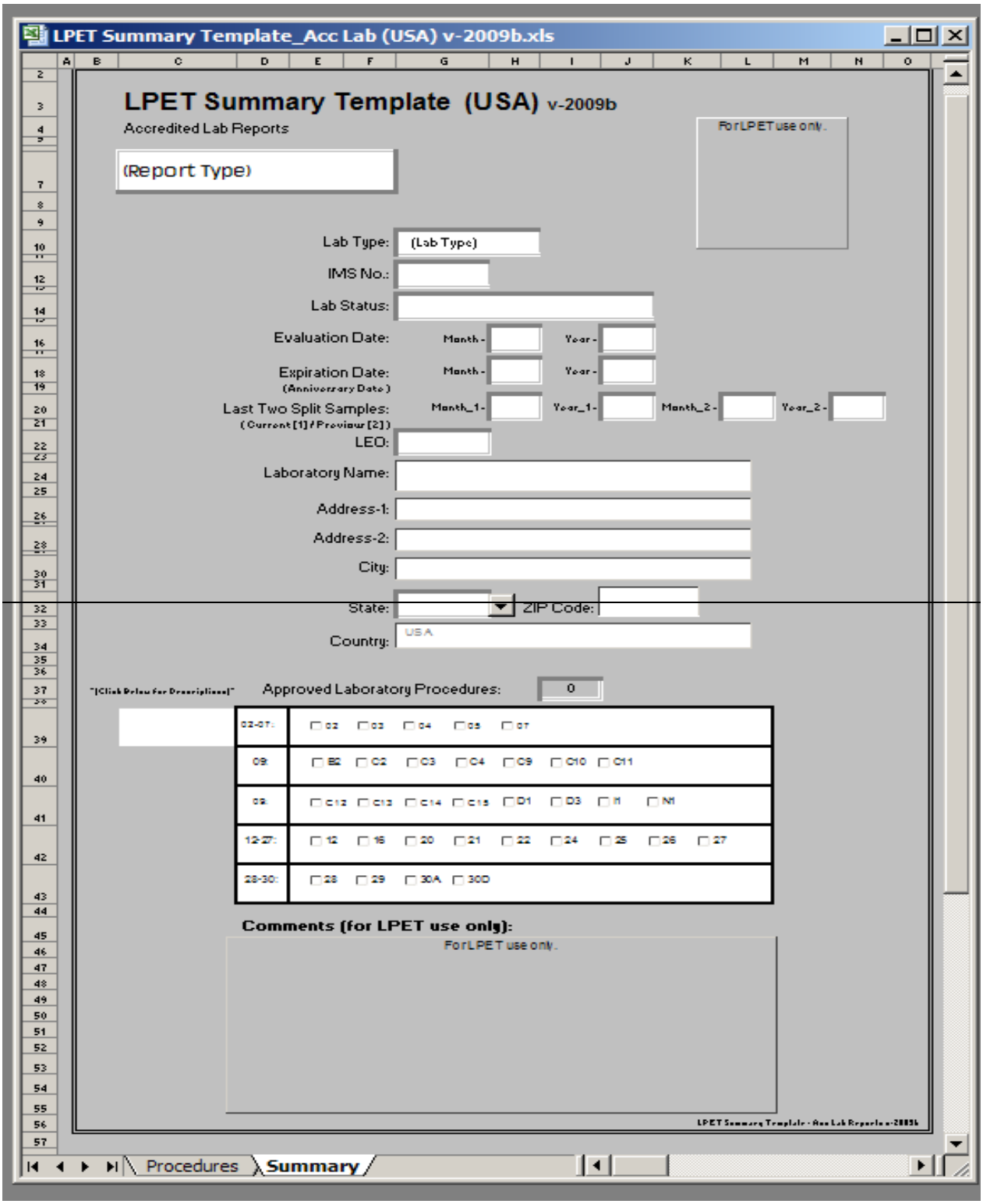
To maintain approve status, analysts must successfully participate in annual milk split sample performance evaluation provided by the Industry Supervisor or a State Laboratory Evaluation Officer for all procedures for which approval has been granted.

CONCLUSION:

Although the procedures, records and/or equipment in use at the time of the evaluation were in substantial compliance with the requirements of the Grade "A" Pasteurized Milk Ordinance, the analyst/facility deviations noted must be corrected. This laboratory is approved, pending correction of the deviations and receipt of a letter detailing the corrections made. Upon receipt of a satisfactory written response and other appropriate documentation detailing the corrective actions taken on or before {***Month Day(s), Year*** *- specified date usually 60 days from expected receipt of the narrative report*}, fully approved status will be granted.

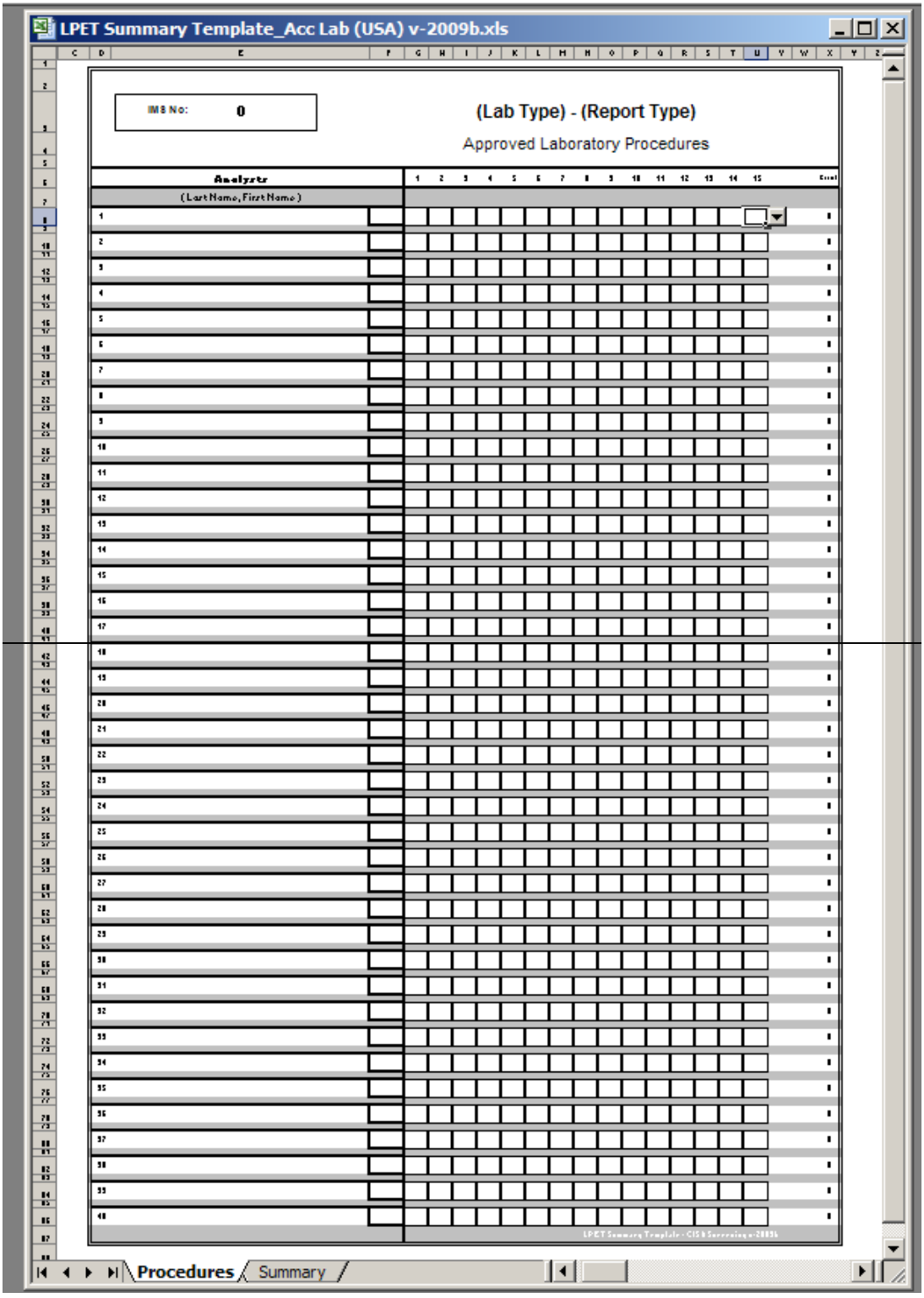
Page 37:

FDA SUMMARY TEMPLATES



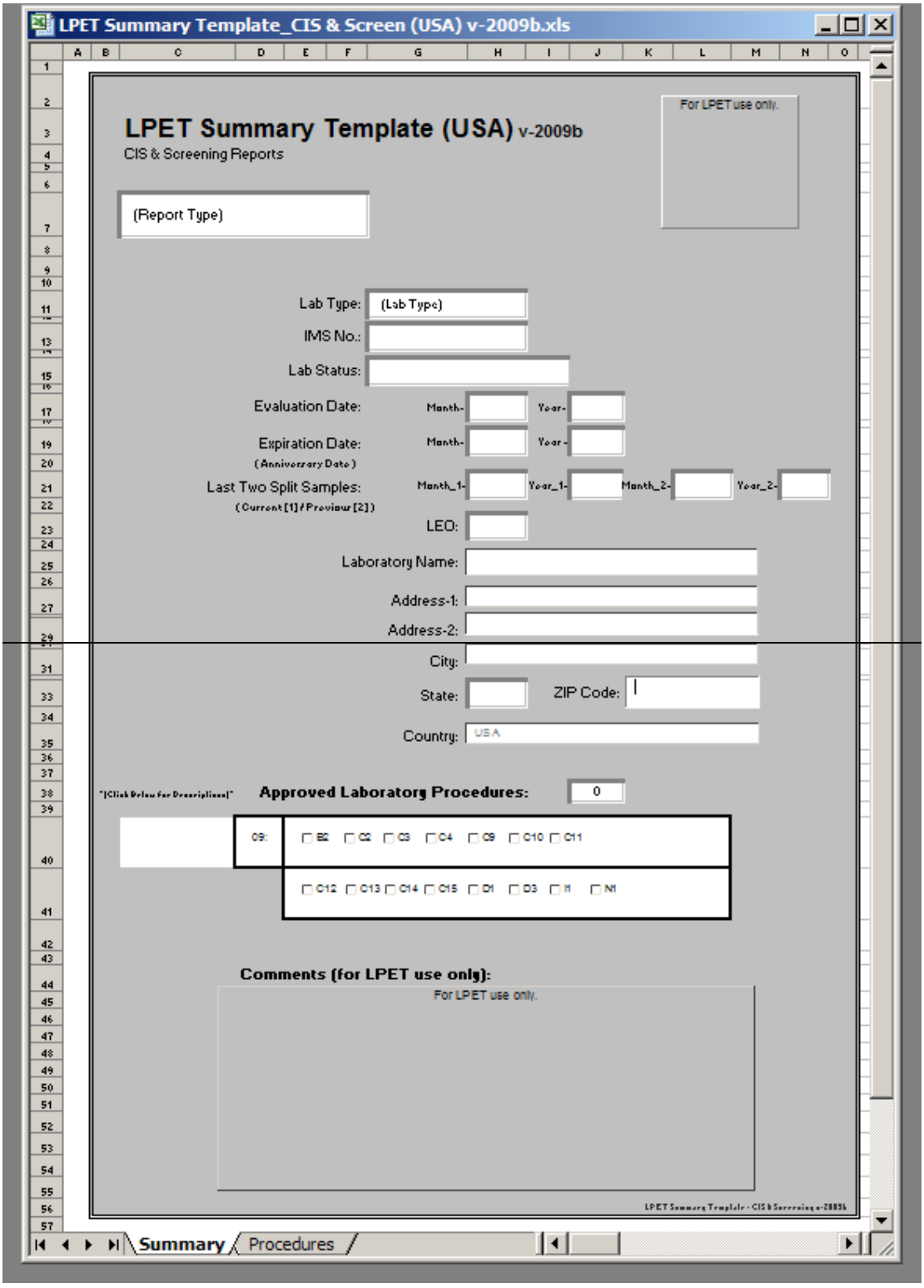
~~Figure 1: Summary sheet, LPET Summary Template_AccLab (USA) v-2009b.xls~~

Page 38:



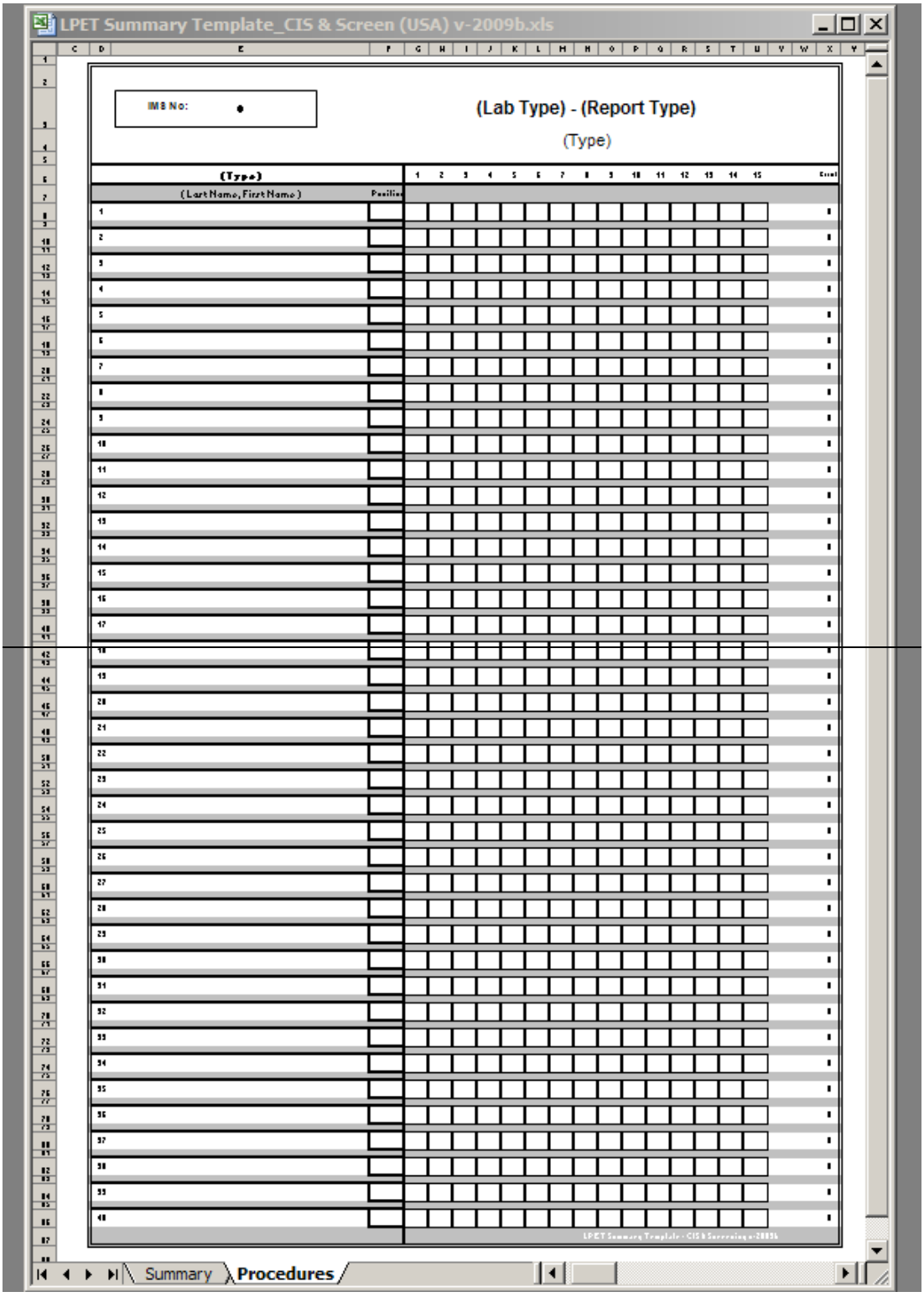
~~Figure 2: Procedures sheet, LPET Summary Template_AccLab (USA) v-2009b.xls~~

Page 39:



~~Figure 3: Summary sheet, LPET Summary Template_CIS & Screen (USA) v-2009b.xls~~

Page 40:



~~Figure 4: Procedures sheet, LPET Summary Template_CIS & Screen (USA) v-2009b.xls~~

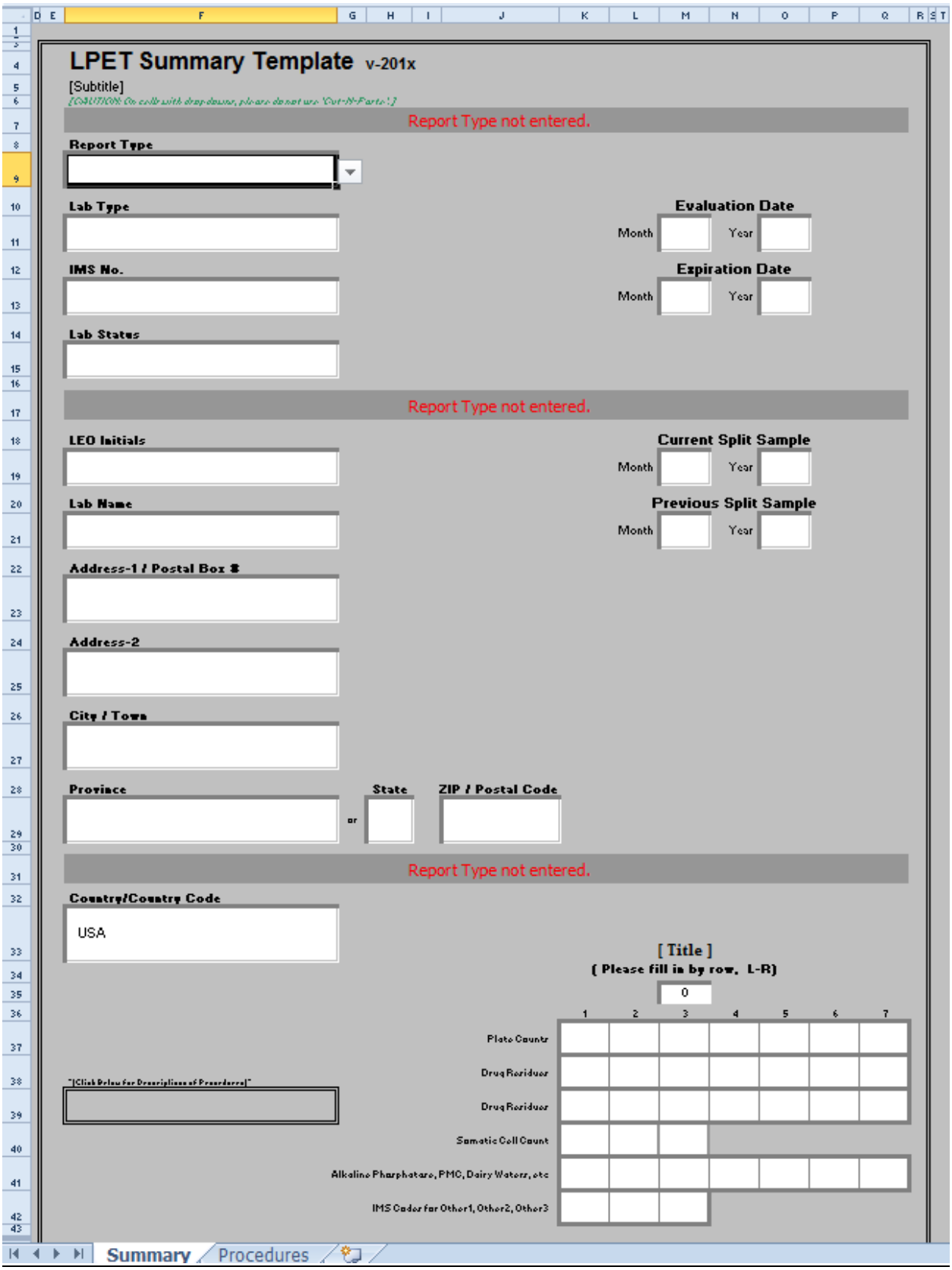


Figure 1: Summary sheet, LPET Summary Template_v-201x.xls

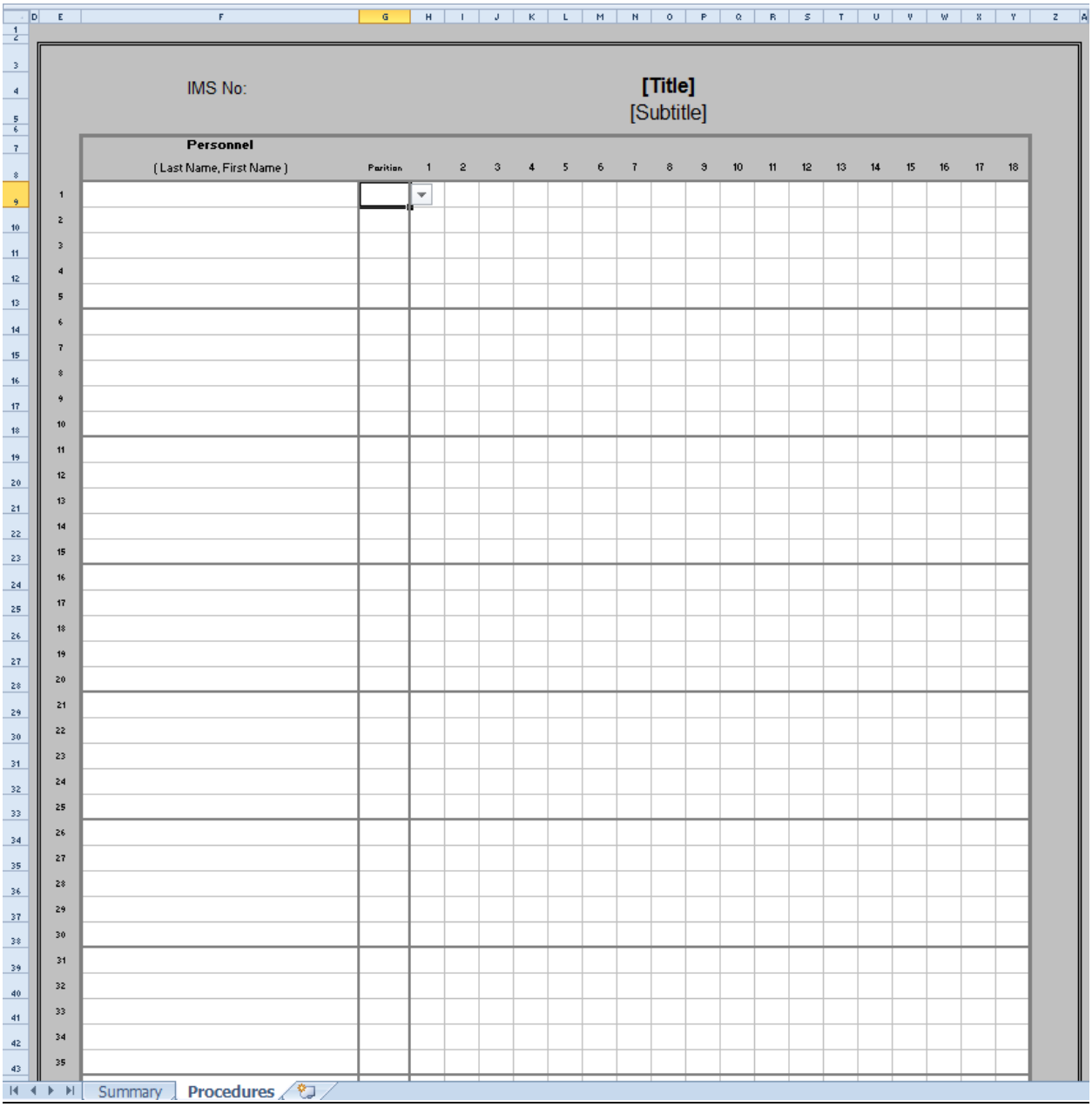


Figure 2: Procedures sheet, LPET Summary Template_v-201x.xls

Name:	CFSAN		
Agency/Organization:	Food and Drug Administration		
Address:	5100 Paint Branch Parkway		
City/State/Zip:	College Park, MD 20740		
Telephone No.:	(708) 728-4114	E-mail Address:	Thomas.Graham@fda.hhs.gov

34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	216
Committee:	Lab

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This Proposal will reduce the number of vitamin split samples from three (3) to two (2) per year. In addition it will change the evaluation of data from the current fixed limit system to the more flexible z-scores base on statistical methods utilized in ISO Standards.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

To more effectively oversee and operate the vitamin milk laboratory program and to accommodate FDA/LPET's demanding Proficiency Testing (PT) Program, the frequency of vitamin split samples is being proposed to be reduced from three (3) to two (2) per year. The number of samples will be modified slightly to accommodate this change. In addition, FDA/LPET has collected sufficient data to demonstrate that the method used to evaluate vitamin milk laboratory performance needs to be changed. FDA/LPET is proposing that the data be evaluated and laboratory status using z-scores, which are based on ISO Standards, that as are used by other chemistry PT programs.

C. Proposed Solution

Changes to be made on page(s): 10-14, 27 & 28 of the (X - one of the following):

	2011 PMO	X	2011 EML
	2011 MMSR		2400 Forms

2011 Procedures 2011 Constitution and Bylaws

MAKE THE FOLLOWING CHANGES TO THE EML:

~~Strike through~~ text to be deleted and underline text to be added.

SECTION 2: PROFICIENCY TESTING PROGRAMS

Page 10:

SPLIT SAMPLE ANALYSIS

The Standard Plate Count (SPC), Petrifilm Aerobic Count (PAC), Plate Loop Count (PLC), BactoScan FC Count (BSC), Spiral Plate Count Loop Method (SPLC), Direct Microscopic Somatic Cell Count (DMSCC), Electronic Somatic Cell Count (ESCC)~~,~~ and Electronic Phosphatase Count ~~and Vitamin A and D_3~~ result of each certified analyst shall fall within the limits shown in Table 2, page 28. The Vitamin A and D_3 result of each certified analyst shall be evaluated by z-scores, which are based on ISO Standards, and are calculated for each individual set of split samples.

The steps for statistical analysis of split sample results are as follows: …

2. Calculate the logarithmic mean for the ~~Standard Plate Count~~ SPC, ~~Petrifilm Aerobic Count~~ PAC, ~~Plate Loop Count~~ PLC, ~~BactoScan FC Count (~~BSC~~)~~, ~~Spiral Plate Count Method (~~SPLC~~)~~, ~~Direct Microscopic Somatic Cell Count~~ DMSCC, ~~Electronic Somatic Cell Count~~ ESCC, and Electronic Phosphatase Count ~~and Vitamin A and D_3~~ results of each test sample; using a table of common logarithms, list the logarithms of all analyst counts for a given sample. Calculate the mean of the logarithms for the sample. …

Page 11:

6. Analysts certified for vitamin analysis shall meet the acceptance ~~limits (L_1 and L_2) and performance levels shown in Tables 2 and 3, page 28~~ criteria using z-scores. …

8. The annual proficiency testing (PT) program for vitamins A and D_3 shall be based on z-scores following ISO Standards. Data shall be converted to log base 10 values and a consensus mean determined. Based on the data for each PT, standard deviations shall be determined. Acceptable results shall be within plus or minus two (2) standard deviations.

ANALYST PERFORMANCE LEVEL

Analysts certified to perform the examinations required by the "Grade 'A' PMO" shall meet the following performance levels on an annual basis.

1. Analysts certified to perform the ~~Standard Plate Count~~ SPC, ~~Petrifilm Aerobic Count~~ PAC, ~~Plate Loop Count~~ PLC, ~~BactoScan FC Count~~ BSC, ~~Spiral Plate Count Method~~ SPLC, ~~Direct Microscopic Somatic Cell Count~~ DMSCC, ~~Electronic Somatic Cell Count~~ ESCC and Electronic Phosphatase Count ~~and Vitamin A and D_3~~ analysis~~,~~; and BIOs approved to

operate a BactoScan FC shall meet the acceptance limits and performance levels shown in Tables 2 and 3, page 28. …

Page 12:

6. Analysts certified to perform vitamin A and D_3 tests shall detect samples that contain vitamins A and D_3 and shall meet the acceptance limits and performance levels for the calculated z-scores, which are based on ISO Standards. Acceptable results shall be within plus or minus two (2) standard deviations.

Page 13:

SPLIT SAMPLES – CHEMISTRY

VITAMINS

The Grade "A" Vitamin ~~Proficiency Test~~ PT Program is operated by the FDA/LPET. In order to be accredited and be listed, laboratories ~~must~~ shall have analysts who have satisfactorily participated in at least two (2) consecutive split sample analyses and ~~must~~ shall have submitted satisfactory method validation and quality control/quality assurance (QC/QA) information. Participation in proficiency testing alone does not satisfy the criteria for analyst certification and laboratory accreditation.

The Grade ~~A~~ "A" Vitamin ~~Proficiency Testing~~ PT Program involves the analysis of sets of ~~four~~ six (6) to eight (8) samples sent to participating laboratories every ~~four (4)~~ six (6) months, i.e., ~~three~~ two (2) times a year with a minimum total of twelve (12) samples. Certification status is based in part on the ability of analysts to analyze samples and have their results fall within limits, ~~(L_1=0.300 and L_2=0.200, based on the statistical parameters set at the 1995 NCIMS Conference in St. Louis, MO)~~ which are evaluated using z-scores that are based on ISO Standards and calculated for each set of split samples. Conditional certification is granted to an analyst (not to a laboratory) when the analyst has satisfactorily analyzed two (2) sets of samples ~~(eight (8) samples~~ in two (2) consecutive shipments~~)~~. Analysts may have one (1) unsatisfactory result, i.e., miss (out of limits) one (1) sample, and still be considered as having satisfactory performance. After analyzing the next consecutive set of samples the analyst is considered fully certified if ~~no~~ not more than two (2) samples have been missed over the course of a one (1) year period ~~(twelve (12) consecutive samples analyzed)~~.

Once fully certified, analysts maintain certification by satisfactorily analyzing ~~all three (3)~~ both sets of split samples each year. During the course of the year full certification is maintained if ~~no~~ not more than two (2) samples ~~(of 12)~~ are missed. Failure without cause to analyze all ~~twelve (12)~~ samples during the course of the year ~~will~~ shall result in the down grading of an analyst's status. It is imperative that laboratory schedules be set up to allow for the analysis of these samples. If a fully certified analyst misses more than two (2) samples ~~(of 12)~~ then that analyst ~~will~~ shall be down graded to provisional certification. Full certification ~~will~~ shall be regained if that analyst misses ~~no~~ not more than one (1) sample of the next ~~eight (8)~~ set of samples that he/she analyzes. Provisionally or conditionally certified analysts that miss more than one (1) sample in the next ~~eight~~ set of samples analyzed after receiving the respective status ~~will~~ shall have their certification/approval removed.

Once certification/approval is removed an analyst may only regain conditional certification by satisfactory performance on the next ~~eight~~ set of samples, i.e., miss ~~no~~ not more than one (1) sample. Full certification requires that the analyst meet the criteria described above.
For split sample purposes each analyst ~~must~~ shall independently analyze the samples. Routine analysis may be performed by multiple analysts working together or by partitioning duties. Certified analysts are responsible for conducting official analysis. Non-certified analysts may assist in analysis but may not solely perform official analyses or report official results.

Re-entry of laboratories that have voluntarily withdrawn or laboratories that have had their accreditation removed ~~is~~ are subject to meeting all of the requirements needed ~~from~~ for a new laboratory, including all quality control (QC) information. It is the responsibility of the laboratory to inform the FDA/LPET when a certified analyst is no longer employed at that laboratory. A laboratory that loses all of their certified analysts is no longer accredited to do official work and ~~must~~ shall seek new laboratory entry prior to resuming official analysis.

Page 14:

An acceptable annual proficiency testing program shall consist of the analyst examining pasteurized milk and milk products for Vitamins A and D_3, a minimum of ~~four (4)~~ six (6) samples ~~three (3)~~ two (2) times a year ~~for a total of twelve (12) samples annually~~ using the methods developed by the FDA, or methods that give statistically equivalent results to the FDA methods, for which the analyst has been approved, unless excused for due cause. The laboratory tests and recommended duplicates of samples are shown in Table 1, page 27.

Page 27:

TABLE 1: SPLIT SAMPLE COMPOSITION

PRODUCTS	**NUMBER OF SAMPLES**	**DUPLICATES**	**ANALYSIS**	**NUMBER OF PRODUCT SAMPLES ANALYZED**
HVD, or 2%, or Skim	3	1	Plate Count /Coliforms	3
			Phosphatase	1
			Vitamins	~~3~~ 1-8
Cream, heavy	2	1	Plate Count /Coliforms	2
			Phosphatase	2
			Vitamins	~~2~~ 1-8
Cream, light	2[a]	0 or 1	Plate Count /Coliforms	1
			Phosphatase	2[b]
			Vitamins	~~1~~ 1-8
Chocolate	2	1	Plate Count /Coliforms	2

			Phosphatase	1
			Vitamins	~~2~~ 1-8
Raw	6	3	Plate Count	6
Raw	8	4	Inhibitors	8
			Somatic Cells	8
			Added Water[c]	8
Dairy Water	8	4	Coliforms	8
			Heterotrophic Plate Count	8
Milk Totals	23[a]	10 or 11	Plate Count	14
			Coliforms	8
			Phosphatase	6
			Vitamins	~~8~~ 12-16
			Inhibitors	8
			Somatic Cells	8
			Added Water[c]	8
Dairy Water Total	8	4	Coliforms	8
			Heterotrophic Plate Count	8

a - One (1) of these samples serves as the temperature control (TC).
b - These two (2) samples are tested for both residual and reactivated phosphatase.
c - This analysis is optional.

Page 28:

TABLE 2: STATISTICAL LIMITS

TEST	**REJECTION LIMIT 1 (L_1)***	**REJECTION LIMIT 2 (L_2)***
Plate Counts	0.268	0.179
Direct Somatic Cell Count	0.300	0.200
Electronic Somatic Cell Count	0.212	0.143
Vitamins**	~~0.300~~ N/A	~~0.200~~ N/A
Electronic Phosphatase Count	0.300	0.200
Dairy ~~water~~ Water MPN	0.949	0.632
Heterotrophic Plate Count	0.300	0.200

* To be used with logarithmic mean.
** Limits for vitamin test results shall be based on z-scores. Acceptable results shall be within plus or minus two (2) standard deviations.

Name: CFSAN

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34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	217
Committee:	Lab

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

To add the formulas for the statistical limits on Table 2 in the 2011 EML (Evaluation of Milk Laboratories). These formulas will need to be provided by the FDA/LPET.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

The rationale for adding the formulas that are embedded in the current Fortran 77 programs in use to determine the rejection limits is to make them available to all State programs in need of them. The Fortran 77 programs are cumbersome to use and much more difficult to fix mistakes than are more current programs such as MS Excel which are easier to input and fix errors.

A concern is that if any of the Fortran files are not functioning properly, there is no way to know this. It seems as though we are blindly using old disks from over a decade ago. With all of the changes to computers and operating systems, many are not comfortable that they there is proof that these files have not been corrupted in some way.

C. Proposed Solution

Changes to be made on page(s): 28 of the (X - one of the following):

	2011 PMO	x	2011 EML
	2011 MMSR		2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

To add the formulas for each of the rejection limits on page 28 of the EML after Table 2. [These would be provided from FDA.]

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Telephone No.: 512-992-5632 E-mail Address: Catherine.hall@dshs.state.tx.us

34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	218
Committee:	Lab

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

Take CIS names off the IMS List.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Only ten CIS (Certified Industry Supervisor) names are shown on the IMS List. There are numerous facilities with greater than ten CISs. Any personnel needing to check if a CIS is listed will not be able to find that CIS on the list if they are the eleventh or later name on the list. They will have to check with the LEO or refer back to the last laboratory survey report.

Certified analysts names are not listed nor are IS (Industry Supervisors) or IA (Industry Analysts).

There is no public health significance.

C. Proposed Solution

Changes to be made on page(s): 25 of the (X - one of the following):

	2011 PMO	x	2011 EML
	2011 MMSR		2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

Take the CIS names off of the IMS List.

Page 25 – 2011 EML:

The narrative report sent to FDA/LPET must be accompanied by the appropriate, completed FDA summary template for the laboratory, specifically representing the information required for verifying and updating the IMS List of accredited laboratories ~~and CISs~~ along with other useful information to be used by FDA/LPET. Only the current revision of the FDA summary templates, authored by FDA/LPET, may be used. There are two FDA summary templates: one for full service laboratories and one for Appendix N Screening Only facilities (CIS and IS). The information captured on the FDA summary template must match the information provided in the narrative report (i.e., IMS number, facility identification, accreditation and certification status, dates, procedures, conclusion, etc.). The information captured may also lend itself to analyst/laboratory tracking and filing by the State LEO.

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34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	219
Committee:	Appendix N

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

"Requests the Chair to assign this proposal to an NCIMS standing committee, special committee, or ad hoc committee as approved by the NCIMS Executive Board."

Proposal to seek information on the requirement of antibiotic testing of pasteurized finished milk and milk products and possible elimination of required regulatory antibiotic testing on pasteurized milk and milk products.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Only 4 days of pasteurized milk and milk products are collected in a 182 day (6 month period). This reflects only a 2% testing of product. This neither represents a screening or deterrence measure. The base milk supply offloaded at plant is where the screening process occurs and all of the regulatory, plant sampler, and 2011 PMO Appendix N resources are applied.

C. Proposed Solution

Changes to be made on page(s): _____ of the (X - one of the following):

_____	2011 PMO	_____	2011 EML
_____	2011 MMSR	_____	2400 Forms
_____	2011 Procedures	_____	2011 Constitution and Bylaws

Would like this proposal assigned to a NCIMS Committee for further study and review. An expected outcome would be a report to the NCIMS Executive Board or issued as a proposal to the 2015 NCIMS Conference if the scientific evidence supports removing the antibiotic sampling of pasteurized milk and milk products.

Name: Fred Nates

Agency/Organization: Virginia Department of Health

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City/State/Zip: Winchester, VA 22603

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34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	220
Committee:	Appendix N

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

To assign a study committee or standing committee to examine the issue when drug residue screening is conducted with an unapproved test (for contractual or export obligations, i.e testing at a level different than the safe/tolerance level) when a Food and Drug Administration (FDA) approved test does exist.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

In 2012, the FDA received a number of inquiries from State Regulatory and Rating Agencies and industry regarding obligations, if any, under the Grade "A" Pasteurized Milk Ordinance (PMO) when drug residue screening is conducted with an unapproved test (for contractual or export obligations, i.e testing at a level different than the safe/tolerance level) when a Food and Drug Administration (FDA) approved test does exist.

C. Proposed Solution

Changes to be made on page(s): _____ of the (X - one of the following):

_____ 2011 PMO _____ 2011 EML

2011 MMSR _____ 2400 Forms

34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	221
Committee:	Appendix N/Lab

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

Assure the US food supply is obtaining imported milk, milk products, and milk ingredients that conform to the same antibiotic and chemical standards as is imparted on the U.S. milk processors and milk producers.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Beginning in 1992, the domestic milk supply was found contaminated with antibiotics. The industry, in union with state & federal regulatory departments jointly adopted methods and rules to test raw tanker loads of milk and spot check final products with accepted methods of the NCIMS and methods implemented by the FDA.

There are thousands of imported milk products from foreign countries yearly into the United States. New Zealand exported $549 million to the U.S. excluding cheese, in 2011, *Cheese Market News, Volume 32, December 21, 2012, Number 48,* is one example of imported milk products. How many of these products or ingredients are used in the Grade A production is not clearly defined. No program has every been delivered to the NCIMS, or to other agencies , showing the antibiotic testing of raw milk or milk products before they are shipped or spot testing after arriving or before use at the processing facilities. This past year the U.S, Food and Drug Administration instituted a testing procedure of analyzing for 26 chemicals, drugs and pesticides. The American dairy system was subject to this governmental oversight to prove milk safety, was the same system used to spot check imported milk and milk ingredients? Another question, are importing nations testing their producers using the same technique(s), allowing for equivalency?

Is the public assured that all foreign imported milk ingredients, milk products or non-graded milk products antibiotic, pesticide and chemical free at the same level that the American Grade A milk products are analyzed and proven to be?

C. Proposed Solution

Changes to be made on page(s): _____ of the (X - one of the following):

_____	2011 PMO	_____	2011 EML
_____	2011 MMSR	_____	2400 Forms
_____	2011 Procedures	_____	2011 Constitution and Bylaws

Delegate a committee to propose a plan to test imported Grade A products and ingredients used in Grade A products consumed in America.

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34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	222
Committee:	Lab

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

Assign a committee to review the EPA Final Revised Total Coliform Rule signed by the EPA Administrator on December 20, 2012 for publication in the Federal Register and report to the 2015 NCIMS Conference on any suggested changes to the PMO.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

The 2011 PMO Appendix D page 160 states: "State Water Control Authority requirements, which are less stringent than the Grade "A" PMO, shall be superseded by the Grade "A" PMO."

EPA Final Revised Total Coliform Rules effective April 1, 2016 eliminates the Maximum Contaminate Level (MCL) for Total Coliform and shift to an MCL for *E. coli*.

The current PMO dairy water program is based solely on Total Coliform standard of <1 per 100 ml and does not even require testing for *E. coli,* does this mean that effective April 1, 2016 that Regulatory Agencies will be required to collect water samples from all public water supplies operating under the EPA or State Administered Drinking Water Programs.

C. Proposed Solution

Changes to be made on page(s): _____ of the (X - one of the following):

_____	2011 PMO	_____	2011 EML
_____	2011 MMSR	_____	2400 Forms
_____	2011 Procedures	_____	2011 Constitution and Bylaws

Assign a committee to review the EPA Final Revised Total Coliform Rule signed by the EPA Administrator on December 20, 2012 for publication in the Federal Register and report to the 2015 NCIMS Conference on any suggested changes to the PMO.

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34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	223
Committee:	2400-Lab

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

Change the ranges for the standards for calibrating/ validating instruments used to provide somatic cell counts in milk to the following: 100-200, 250-350, 400-550, and 650-800. These changes would apply to standards used on all approved electronic cell counters,
If the 2013 Conference adopts a change in the regulatory somatic cell level to a lower value, the hourly check sample would be the one that falls most closely in line with the newer regulatory level. (Example: If the Conference reduces the regulatory level for Grade A raw milk to 600,000 per ml, the hourly check sample will be the 650-800 level. If the regulatory level is changed to 400,000 per ml, the hourly check sample will be the 400-550 level.)
If the 2013 Conference does not adopt a change in the regulatory level for somatic cells in raw milk, the current levels for standards for electronic somatic cell counts would remain as they are currently listed.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

There is no public health significance to this change.

C. Proposed Solution

Changes to be made on page(s): _____ of the (X - one of the following):

_____	2011 PMO	_____	2011 EML
_____	2011 MMSR	XX	2400 Forms
_____	2011 Procedures	_____	2011 Constitution and Bylaws

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	2011 Procedures		2011 Constitution and Bylaws

The NCIMS Chair is to appoint a study committee or assign to a standing committee to examine the issue when drug residue screening is conducted with an unapproved test for contractual or export obligations and at a testing level different than the safe/tolerance level, when a Food and Drug Administration (FDA) approved test does exist.

The appointed study committee or assigned standing committee will provide a report on the topic at the 35th National Conference on Interstate Milk Shipments in 2015. The report will examine current obligations under the Grade "A" Pasteurized Milk Ordinance and may propose additional requirements via a formal proposal.

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34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	224
Committee:	2400-Lab

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

Modify IDEXX New SNAP Beta-Lactam (NBL) test kit shipping requirements in the 2400 form to allow non-refrigerated test kit shipments. NCIMS 2011 Conference passed proposal (229) to allow test kit manufacturers to ship antibiotic test kits unrefrigerated when it is demonstrated that the test kit performs as labeled after the kit has been heat stressed and real-time storage through end of test kit shelf life.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Current SNAP NBL test kits are shipped on ice in styrofoam lined boxes. This adds a considerable amount of packaging material to each shipment that becomes waste. The special packaging also adds cost and processing steps for customers. These extra costs and steps can be avoided by shipping the kits at ambient temperature and storing kits refrigerated once they reach the customer.

Following the previously approved FDA ambient ship protocol, IDEXX collected data to support ambient shipping temperatures for the SNAP NBL test kit.

To simulate the extremes of temperature excursions that may be experienced by the test kits during ambient shipping, three lots of test kits were stored at 37°C for 72 hours and then returned to refrigerated storage. Additionally, the same three lots of test kits were placed at 45°C overnight (~17 hours). These lots were tested at kit expiration for function to simulate an extreme temperature excursion.

To demonstrate the functional stability of the SNAP NBL test kit over its life after simulated

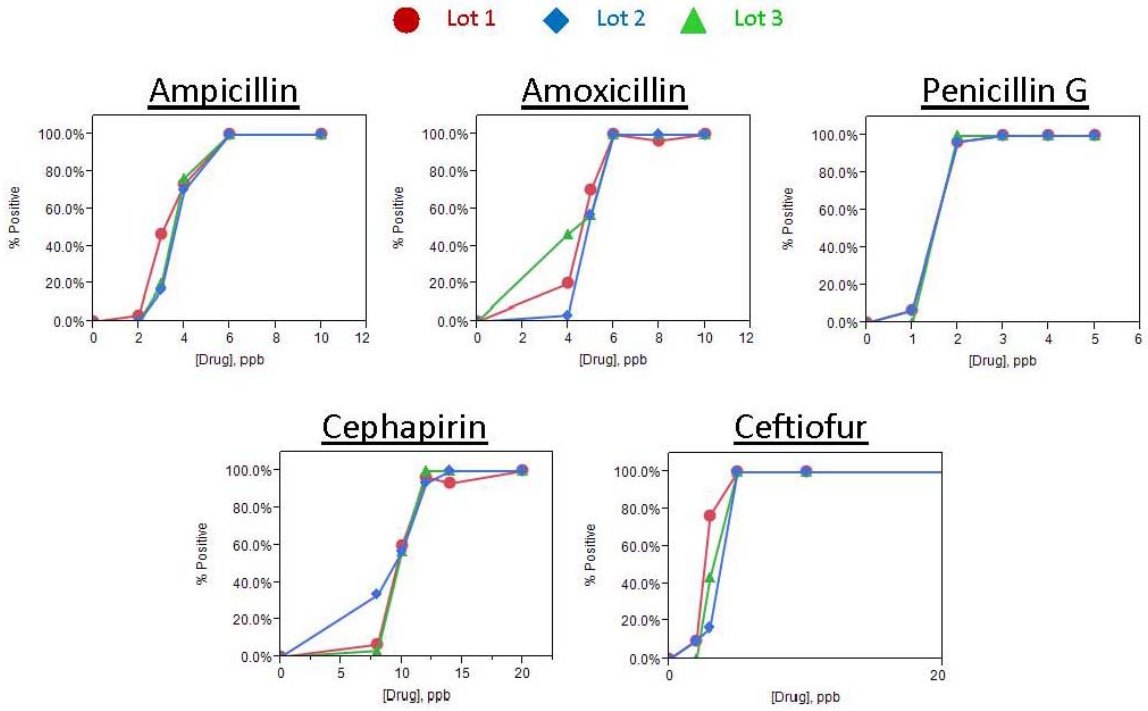
ambient shipping stress, dose response curves were collected for 5 different drugs before and after heat stress and again at the end of kit life. Three manufacturing lots of SNAP NBL were tested. For each dose response curve, 60 negative replicates and 30 replicates of fortified samples at a minimum of 5 drug concentrations were run. The 90% positive levels with 95% confidence were calculated and are shown in Table I. Table II shows the dose response curves of three lots of SNAP NBL test kits after 45°C stress. Throughout the study, all negative samples gave negative results on the SNAP NBL (i.e. no false positives were observed).

Table 1. Comparing Three Lots of SNAP NBL 90/95 Results to the package insert, at manufacture, post 72 hour at 37^0C and 9 months at 4^0C after the 37^0C (72 hrs) stress.

	90/95 in parts per billion (ppb) for the NBL SNAP kit.			
Lot # LG613	Package Insert	At Manufacture	hours at 37 C	stress and 9
Penicillin G	3.0	2.1	2	2.2
Amoxicillin	7.3	5.8	6.8	6.8
Ampicillin	5.8	5.3	5.1	4.2
Cephapirin	11.7	12.2	11.8	12.2
Ceftiofur*	12*	5	4	4.1
	90/95 in parts per billion (ppb) for the NBL SNAP kit.			
Lot # JG425	Package Insert	At Manufacture	hours at 37 C	stress and 9
Penicillin G	3.0	1.6	2.1	2
Amoxicillin	7.3	5.6	6.4	5.8
Ampicillin	5.8	4.9	5	3.9
Cephapirin	11.7	12.3	12.3	12.8
Ceftiofur*	12*	4.1	3.8	3 - 4
	90/95 in parts per billion (ppb) for the NBL SNAP kit.			
Lot # KG217	Package Insert	At Manufacture	hours at 37 C	stress and 9
Penicillin G	3.0	2.3	2	2.5
Amoxicillin	7.3	7.3	6.8	5.4
Ampicillin	5.8	5.7	4.8	4.9
Cephapirin	11.7	13.7	12	12.6
Ceftiofur*	12*	5	4.3	3.7

* The data in the package insert was based on incurred ceftiofur.
Testing for this study used the parent drug.

Table 2. Dose response curves for three lots of SNAP NBL kits stored at 45°C overnight.



Summary :

Over 10,000 devices were run during this study. The results show that the SNAP NBL kit performs to label claims after being subjected to extreme temperature excursions that may be encountered during ambient shipping.

- 90/95 results are consistent at Manufacture, Post-Stress and End-of-Life test points
- SNAP NBL performance is consistent from Lot-to-Lot

- Overnight stress (17hrs) at 45^0C showed similar performance at End of Life testing

- The data support shipping SNAP NBL kits at ambient temperature. This will reduce waste and lower costs for our customers

C. Proposed Solution

Changes to be made on page(s): Page 1 of the (X - one of the following):

	2011 PMO		2011 EML
	2011 MMSR	X	2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

Remove IDEXX New SNAP Beta-Lactam 2400, page 1, Apparatus & Reagents, Section 3. Equipment, item f. and re- letter remaining Section 3. Items.

~~f. Kits received refrigerated~~
~~g~~. f.
~~h~~. g.
~~i~~. h.

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34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	225
Committee:	2400-Lab/ Other Species

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

Modify IDEXX New SNAP® Beta-Lactam Test 2400 form to include raw, commingled goat milk samples.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

The IDEXX New SNAP Beta-Lactam (SNAP NBL) test kit has been approved for raw, commingled cow milk under the provisions of the PMO since 2003. Customers have requested SNAP NBL be evaluated with goat milk for official use in NCIMS milk-regulatory programs. Obtaining a goat milk approval is an Other Species label claim extension to the currently approved IDEXX SNAP NBL test kit.

Following the NCIMS practices and policies allowed for approval of Other Species milk screening, the study protocol was approved by FDA-CVM and Dr. Steve Zeng of Langston University who conducted the goat milk evaluation.

The validation included testing fortified goat milk samples at early, mid and late lactation intervals, incurred milk samples and frozen milk samples.

<u>Fortified Goat Milk Sample Summary</u>

Pooled milk from 6 goats was collected during mid lactation. Milk was confirmed negative at an Independent Lab. Dose curves were collected by fortifying milk with Amoxicillin, Ampicillin, Cephapirin, or Penicillin G. Sixty negative samples were run and 30 samples were run at each of 6 or more drug concentrations. All unfortified milk samples gave negative

results on the NBL SNAP (0 positive/ 60 negative samples). The results at each dose are given in Table I. All samples fortified to the US FDA tolerance and/or safe levels gave positive results.

Table 1. Results of drug-fortified goat milk during mid-lactation.

	Positive	Negative
Raw milk (60 replicates)	0	60
Ampicillin		
10 ppb (30)	30	0
8 ppb (30)	30	0
7ppb (30)	30	0
6 ppb (30)	30	0
5 ppb (30)	30	0
4 ppb (30)	30	0
Amoxicillin		
10 ppb (30)	30	0
8 ppb (30)	30	0
7ppb (30)	30	0
6 ppb (30)	30	0
5 ppb (30)	30	0
4 ppb (30)	30	0
Cephapirin		
20 ppb (30)	30	0
14 ppb (30)	30	0
13 ppb (30)	28	2
12 ppb (30)	30	0
11 ppb (30)	30	0
10 ppb (30)	30	0
9 ppb (30)	30	0
8 ppb (30)	28	2
Penicillin G		
5 ppb (30)	30	0
4 ppb (30)	30	0
3 ppb (30)	30	0
2.5 ppb (30)	30	0
2 ppb (30)	30	0
1 ppb (30)	25	5

In addition to mid-lactation sample, Penicillin G fortified milk from early and late lactation was evaluated. SNAP NBL gave positive results for all samples fortified at the US safe level for both early and late lactation. All 60 negative samples gave negative results (i.e. no false positives were observed).

Incurred Goat Milk Samples Summary

Fifteen (15) mid lactating goats were used for the incurred study. Three goats were used as the control group. Each drug (Amoxicillin, Ampicillin, Cephapirin, and Penicillin G) was administered to three goats. Milk from all goats was screened using the SNAP NBL kit after treatment. Samples were positive after treatment. All milkings gave negative results by the 7th milking. Note: Positive results were observed at initial milking with the untreated control goats; all results were negative at subsequent milkings.

Frozen Goat Milk Samples Summary

Milk from mid-lactation was fortified with various concentration of Ampicillin and milk from late-lactation was fortified with Penicillin G. Unfortified and fortified samples were frozen at -20°C, thawed and tested at 30 and 60 days using the SNAP NBL. A minimum of 2 replicates were run at each testing event. All samples tested appropriately (unfortified milk gave negative results, fortified samples gave positive results).

Conclusion

The validation work that has been completed indicates that the SNAP NBL kit will reliably give negative results on goat milk that does not contain the regulated beta-lactams. The SNAP NBL kit will also reliably give positive results with goat milk samples containing beta-lactam antibiotics that are at or above the US FDA safe/tolerance levels for cow milk. The validation work does indicate that the SNAP NBL kit is more sensitive when screening goat milk as compared to cow milk samples containing the same concentration of antibiotic.

C. Proposed Solution

Changes to be made on page(s): Pg 1. Title of the (X - one of the following):

	2011 PMO		2011 EML
	2011 MMSR	X	2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

Modify the IDEXX New SNAP Beta-Lactam 2400, title section for the milk sample.

(raw commingled cow, ~~and~~ raw commingled camel and raw commingled goat milk)

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34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	226
Committee:	2400-Lab

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

To update FORM FDA 2400h-4 Advanced Instruments SomaScope MKII/Smart Rev 3/11, titled "ELECTRONIC SOMATIC CELL COUNT Somascope MKII/SomaScope Smart" to include the new platform CombiScope FTIR which comprises the SomaScope Smart and the LactoScope FTIR. The SomaScope Smart instrument on this platform is an exact reproduction of the stand-alone SomaScope Smart.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

To update FORM FDA 2400h-4 Advanced Instruments SomaScope MKII/Smart Rev 3/11, titled "ELECTRONIC SOMATIC CELL COUNT Somascope MKII/SomaScope Smart" to include the new platform CombiScope.

C. Proposed Solution

Changes to be made on page(s): Pages 1,4,5,8 of the (X - one of the following):

	2011 PMO		2011 EML
	2011 MMSR	x	2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

Modify the 2400 Form, page 1, Title.
Title: Somascope MKII/SomaScope Smart/CombiScope

Modify the 2400 Form, Page 1 of 9, Section 3, Automated Electronic Somatic Cell Counters, item d.
d. CombiScope

Modify the 2400 Form, page 4 of 9, Section 7, Other Working Solutions, a. Detergent Container, item 2.
2. SomaScope Smart/CombiScope

Modify the 2400 Form, page 5 of 9, Section 7, Other Working Solutions, b. Water Container(s), 5. Dispense, item c1.
c) CombiScope
1. Pour the solution above into the "Triton Water" containers provided with the instrument

Modify the 2400 Form, page 5 of 9, Section 8, Somatic Cell Counter, b. Instrument Initiation, items 3a-e.
3. CombiScope
a. The CombiScope instrument is designed to be turned on at all times
b. Turn on the personal computer (PC)
c. Key in the defined password for the respective user
d. Double-click the CombiScope icon to start up the user interface
e. Perform a zero and clean sequence

Modify the 2400 Form, page 8 of 9. Section 13, Shut down procedure, items c1-5.
c. CombiScope
1. The CombiScope instrument is designed to be turned on at all times
2. Perform a clean cycle twice
3. Clean the auto sampler
4. Switch off PC
5. Put instrument pipette in beaker of Triton Water solution (item 7b)

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34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	227
Committee:	2400-Lab

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

Add the laboratory IMS test code to each of the 2400 Series Forms.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

LEOs use a number of the 2400 Series forms and do not always have the codes memorized. By having the codes on the form, the LEO would then be able to put it on the narrative report without having to spend time looking it up.

C. Proposed Solution

Changes to be made on page(s): 1st page of each of the (X - one of the following):

	2011 PMO		2011 EML
	2011 MMSR	x	2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

The NCIMS Laboratory Committee in conjunction with FDA/LPET will add the IMS test codes to each of the 2400 Series Forms.

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34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	228
Committee:	2400-Lab/ Other Species

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

To allow for beta lactam drug residue testing of sheep milk, that had previously been stored frozen using methods validated for sheep milk, provided the milk is sampled in accordance with an approved sampling and handling protocol.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Sheep by their physical size and short lactation period produce small volumes of milk. Due to this many farms and processing facilities freeze milk and store it in bags until a sufficient quantity is accumulated for processing. Freezing sheep milk prior to processing has been an acceptable and often necessary practice. The make-up of sheep milk makes this acceptable from a milk quality standpoint and there is no public health concern from the practice. The frozen milk is then shipped from the farm to the processor on wrapped pallets.

FDA publication M-I-10-6 (Qs/As 2009) disallows the thawing and subsequent testing of sheep milk stating "the Charm SL drug test kit was not validated by CVM for use with frozen raw sheep milk. The raw sheep milk must be tested prior to freezing." A portion of the validation of the Charm SL test kit was in fact conducted by using frozen raw sheep milk. During the incurred portion of the validation study, milk from treated animals was collected and frozen. It was thawed for drug quantitation by the Charm BSDA method and refrozen. It was further diluted with frozen-thawed commingled sheep milk to make samples at safe level tolerances and fractions of safe level/tolerances and then divided and frozen. Frozen samples were sent to the independent testing laboratory and thawed for analysis. This procedure was submitted to and approved by FDA-CVM prior to the start of the validation study. In addition to this, the FDA 2400 Form "Charm SL, SL6, SL3 Beta Lactam Tests" Item 5 "Reagent Stability" specifically provides for the use of frozen control samples so long as the control samples are held at proper

temperatures, thawed slowly under refrigeration and used within 24 hours. In the initial studies of the Charm SLBL, the method was validated to work with frozen controls. The frozen control samples were tested and found to be stable up to 60 days.

There is no problem with the testing of sheep milk that has been frozen. The questions have been around sampling and handling. Therefore this proposal suggests an approval process for a protocol that can be used to assure the appropriateness of the sample. A standard protocol is not practical as there are differences in the way milk is handled for different purposes but there can be agreement on the basics of what must be in the protocol.

C. Proposed Solution

Changes to be made on page(s): _____ of the (X - one of the following):

_____	2011 PMO	_____	2011 EML
_____	2011 MMSR	X	2400 Forms
_____	2011 Procedures	_____	2011 Constitution and Bylaws

Make changes to the Form FDA 2400n – Appendix N General Requirements to reflect that samples of previously frozen sheep milk may be tested using methods validated for sheep milk, provided the sheep milk is sampled in accordance with an approved sampling and handling protocol. Also, make changes to Form FDA 2400n-1 Charm SL / SL6 / SL3 to reflect that samples of previously frozen sheep milk can be officially tested using the Charm SLBL method after properly thawing using the same instructions as given for control samples provided the sheep milk is sampled in accordance with an approved sampling and handling protocol.

This protocol shall be approved by the receiving state's regulatory authority and must address the following items:

- Sampling protocol that assures a representative sample including, but not limited to, the certification or licensing of the person (s) obtaining the samples
- Storage protocol that assures the sheep milk is frozen within 24 hours of sampling
- Storage at or below -15°C
- Samples delivered to the laboratory for testing within 60 days of freezing the sheep milk
- Adequate chain-of-custody to assure sample identification and handling
- Copies of the SOP are available at the farm, the receiving plant and the laboratory performing the testing

34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	229
Committee:	2400-Lab

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

Add procedure for the re-hydration of Dry Milk Product Samples to the Petrifilm Aerobic, Coliform and High Sensitivity Coliform Count 2400 series form

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

If M-a-98 is approved, the testing matrix indicates that Petrifilm can be used to test Dry Milk Product Samples, but the 2400 series form does not include the procedure for proper re-hydration of dry milk product samples prior to plating.

C. Proposed Solution

Changes to be made on page(s): 2400a-4 Page 7 of 13 of the (X - one of the following):

	2011 PMO		2011 EML
	2011 MMSR	X	2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

12. Samples Other than Milk _____

a. Weigh 11g aseptically into a 99mL dilution blank heated to 40-45°C _____

13. Dry Milk Product Samples _____

a. Weigh 11 g aseptically into a 99 mL dilution blank heated to 40-45 °C _____

1. Use standard dilution blank _____

2. Or, 2.0 % sodium citrate blank (pH<8.0) for relatively insoluble sample (e.g. whey) _____

b. Wet sample completely with gentle inversions _____

c. Let soak a minimum of 2 min; shake 25 times in 7 sec with a 1 ft movement; use within 3 min of agitation _____

INCUBATION

~~13~~ 14. Incubating Petrifilm Plates (see CP item 15) _____

a. Stack plates in horizontal position, clear side up _____

1. PAC/PCC – no more than 20 high _____

2. HSCC – no more than 10 high _____

b. Incubate within 10 min _____

1. PAC - 48±3 hours at 32±1°C _____

2. PCC/HSCC - 24±2 hours at 32±1°C _____

Renumber all Subsequent Items

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34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	230
Committee:	2400-Lab

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

Revise FDA 2400; Pasteurized Milk Containers rev. 1/13. To allow 1 ml of rinse solution be tested for Residual Coliform Count (RCC) when performing the surface swab method examination. The swab tests will still be 10 times more sensitive than the test for 1 gallon milk jugs.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Currently 1 ml of rinse solution is tested for Residual Bacteria Count (RBC) and 3 ml is tested for RCC. In the event of no growth, both RBC and RCC are reported as <1, with RBC getting the added qualification of /50 sq cm. Presumably the logic of this disparity is that the presence of coliform is the more significant of the two.

This test dates from the time when a large percentage of containers were multiple use. At that time, the presence or absence of bacteria could be used to demonstrate the efficacy of the washing and sanitizing process. In todays milk industry the vast majority of containers and closures are single use and are created by processes that are not conducive to bacterial growth.

The test is still a valuable tool in that it can demonstrate improper handling or storage or a

work area with an unacceptable air quality. For this reason, more container manufacturers are requesting a yeast and mold test be performed. The presence of excessive amounts of yeast and mold is more likely than the presence of coliform bacteria. This is a valid and reasonable request, even though it is not a part of the NCIMS program.

Currently the rinse aliquots contain 5 ml of solution. After 1 ml plus 3 ml have been plated for RBC and RCC, less than 1 ml remains because the swab retains a significant amount of the solution. If the test allowed 1 ml to be plated for both RBC and RCC, an adequate amount of rinse would be available for additional testing, e.g., yeast and mold. Plates which show no growth would still be reported as <1 and both RBC and RCC would have the added qualification of /50 sq cm.

C. Proposed Solution

Changes to be made on page(s): _____ of the (X - one of the following):

_____	2011 PMO	_____	2011 EML
_____	2011 MMSR	X	2400 Forms
_____	2011 Procedures	_____	2011 Constitution and Bylaws

Changes to be made on Page 7, 2400; Pasteurized Milk Containers rev. 1/13 as follows:

27. d. For RCC, pipet ~~3~~ 1 mL to a single CPC plate or ~~three~~ 1 mL ~~portions on three~~ into a single PCC ~~plates~~ plate

32. c. Report the count in 31.c as the ~~RCC~~ RCC/50 sq. cm

32. d. If no colonies on RCC plate(s), report as ~~<~~1 <1/50 sq. cm

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34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	231
Committee:	2400-Lab/ Scientific

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

Extend the allowable time for the transportation of water samples from 30 hours to 48 hours for water samples tested in IMS listed laboratories.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Background and Current Standards

The current 30 hour limit for water samples to be tested after collection at times necessitates special trips for water samples to be specially delivered to the laboratory. Over the last several years we have extended the36 hour time for milk samples to be in transit first to 48 hours and then to 60 hours at the 2009 NCIMS conference.

The Environmental Protection Agency (EPA) test procedures require that tests be

started within 30 hours of sample collection. The EPA drinking water program has no mandatory cooling requirement but encourages water samples in transit to be stored at 10^0 C or less. Safe sample standards are established as <1 coliform per 100 ml is satisfactory for drinking water purposes, $\geq$1 coliform per 100 ml is unsatisfactory for drinking water purposes. In the Final Revised Total Coliform Rule signed by the EPA Administrator on December 20, 2012 for publication in the Federal Register the standard for water sample storage during transportation was not changed.

The FDA Pasteurized Milk Ordinance (PMO) requirements are a little more stringent. FDA form 2400m Dairy waters require that samples transported more than 6 hours to be stored at 0-4.4^0 C with temperature control sample when going to a Grade "A" certified laboratory. When going to an EPA certified laboratory samples are not required to be refrigerated but are recommended to be refrigerated at 10^0 C. Sample testing must still begin within 30 hours. Results standards are the same <1 coliform per 100 ml is satisfactory, $\geq$1 coliform per 100 ml is unsatisfactory.

Discussion

Five (5) independent studies cited in this proposal. These studies were directed mainly to justify the need to refrigerate samples to preserve the sample in a truly representative state. Data extracted from the studies also shows that not only does refrigeration preserve the sample but that preserved sample will be truly representative for a longer period of time than is currently accepted. The standard for drinking water accepted during the time period of the studies was a more lenient standard than used currently.

An in house study was also conducted to specifically examine the effects of time on refrigerated samples. This study used both seeded prepared samples and raw natural samples collected from various dairy water sources. The samples were held at 4.4^0 C and tests were conducted at 0, 30, 48, 54, and 72 hour hold times. The in house study also indicated that the temperature preserved sample will be truly representative at 72 hours as well as at 0 hours or 30 hours. There was some variation in microbial counts over the testing period and some between laboratories. However, the variations were not statistically significant from 30 hours to 72 hours after sample collection. At no time did counts decrease to a point that would produce a false negative under current standards.

Data

Several scientific studies were reviewed to obtain data that relates to the effect of hold time on water samples. Generally the studies were done to show either the relationship of ambient temperatures and sample storage or to justify the refrigeration to preserve a sample. The data does support the hypothesis that hold time can be extended without adversely affecting the sample. All of the studies used MF and MPN analysis

techniques except the in-house study which used several types of analysis.

Data found in 2 studies indicate that hold time of unrefrigerated samples up to 48 hours does not significantly change number of positive results.

In a study conducted by S.C. Hsu and T.J. Williams[b] in 1981 over 4658 samples of municipal and private water were analyzed. Hold times were measured in days rather than hours at ambient temperatures. Study findings suggest that cyclical die-off and regrowth patterns may occur over periods of days for some members of the coliform group. The percentage of positive coliform test results did not exhibit regular increases or decreases with increasing sample hold times.

Another study conducted by Jon H. Standridge and Joseph J. Delfino[e] 1983. In this study 3154 samples of private and municipal water were analyzed after 24 hours and 48 hours hold time at ambient temperatures (20 ± 2^0 C). Study findings indicate the total number of coliform-positive samples was unchanged by increasing storage time to 48 hours.

In 3 studies reviewed samples were held at two temperatures ambient temperature and 5^0 C. All of the studies had similar results.

A 1983 study conducted by A.E. McDaniel and R.H. Bordner[c] 50L samples were collected weekly or bi-weekly for 15 weeks. Each sample was broken down into 7 subsamples, one subsample for chemical analysis and 6 for bacteriological analysis. Samples were held at 22^0 C and at 5^0 C and analyzed at 12 hours, 24 hours, and 48 hours. The results as seen in Fig. 4 of this study indicated that the unrefrigerated samples lost significant numbers of bacteria but did not lose enough to produce negative results. The refrigerated samples did not lose significant numbers from 24 hours to 48 hours. In fact the refrigerated samples lost fewer numbers in 48 hours than the unrefrigerated samples did in 24 hours.

Another study conducted by A.E. McDaniels, et. al.[a] had similar results. Over 512 samples were collected from a municipal water supply plus a 50-60 liter samples. Samples were inoculated with E. cloacae and C. freundii. Samples were stored at 5^0 C and at 22^0 C at 24 hours, 30 hours, and 48 hours. The results as seen in Fig. 4 of this study were similar to the 1983 study. The unrefrigerated samples lost significant numbers of bacteria but did not lose enough to produce negative results. The refrigerated samples did not lose significant numbers from 24 hours to 48 hours. In fact the refrigerated samples lost fewer numbers in 48 hours than the unrefrigerated samples did in 24 hours.

A third 1955 study by E. E. Geldreich[d] was reviewed. Samples were taken in winter and summer, 3 each, from six sources farm wells, rivers and a lake for a total of 36 samples. Samples were held at 5^0 C, at room temperature (13^0-32^0 C) and at 35^0 C.

Samples were analyzed at 24 hours, 48 hours, and 72 hours. Results varied in this study but comparing mean ratios as in Table 4 all samples showed significant loss in the first 24 hours, however, the refrigerated samples showed significantly less loss in 48 hours and 72 hours than did the unrefrigerated samples. The ratios still indicate that the loss still would not have produced a negative result under current standards.

The In house study was conducted in 2011. Samples were tested at 4 laboratories the MRC Laboratory, Oklahoma State Department of Agriculture Laboratory, Kansas State Board of Agriculture Laboratory, and the Arkansas Department of Health Laboratory.

A combination of prepared samples and natural samples were used in this study. Well water, chill water from a dairy plant and glycol from a dairy plant was collected to prepare samples to be shipped to the various laboratories. Samples were seeded with *E. coli*, and *K. pneumonia* to achieve a target count of approximately 30 CFU's/100ml. *Pseudomonas aeruginosa* was added to see if it had any effect on coliform survival. All samples were stored and shipped at temperatures between 0-4.4^0 C. Samples were analyzed at 0 hours, 24 hours, 30 hours, 48 hours, 60 hours, 72 hours, and 96 hours.

Different analysis methods were used to compare results. Membrane filtration was used at 2 of the laboratories, Colilert was used at two laboratories, Colisure was used at one laboratory, and MPN was used in three laboratories

The results over all showed that the microbial loss over the analysis period was statistically insignificant. There were a few instances that numbers dropped slightly but not enough to produce a negative result. There was also some instances that a drop in numbers occurred at one analysis time but the count rebounded by the next analysis.

Data extracted from the various studies along with the in-house study would indicate that allowing and extended hold time of up to 60 hours would not have an adverse effect on the number of positive samples. Given current standards and current testing technology none of the data reviewed would indicate an adverse effect on positive samples if the samples were transported and/or held up to at least 48 hours. Some of the data actually indicates a 60 hour hold time is feasible without adverse effects since there appears to be some cyclical loss and growth even under refrigeration during the hold period. Protecting the public health is still served very well. If coliform is present in a sample it will still likely be present at some level above the standard

Conclusion

It is clear that the milk program will continue to use EPA certified laboratories and they will be allowed to accept samples up to 30 hours without refrigeration. As presented in the various papers samples that are refrigerate show less die off at 48 plus hours, possibly out to 72 hours, than those that are held 30 hours without refrigeration. This extended time, necessary for travel from point of collection to laboratory in many

cases, would have little if any effect on the sample on samples currently tested under the dairy water program and these samples will continue to be more representative of the when they were collected verse the 30 hour unrefrigerated samples that we accept the results on that are tested in an EPA certified laboratory.

Literature Cited

a. A.E. McDaniels, R.H. Bordner, P.S. Gartside, J.R Haines, K.P Brenner, C.C. Rankin, Holding Effects on Coliform Enumeration in Drinking Water Samples, Applied and Environmental Microbiology, Oct. 1985

b. S.C. Hsu, T.J. Williams, Mich. Dept. of Public Health, Evaluation of Factors Affecting the Membrane Filter Technique for Testing Drinking Water, Applied and Environmental Microbiology, Aug. 1982

c. A.E. McDaniel, R.H. Bordner, Effects of Holding Time and Temperature on Coliform Numbers in Drinking Water, Research and Technology, Journal AWWA, Sept. 1983

d. E.E. Geldreich; P.W. Kabler,M.D., Ph.D. F.A.P.H.A.; H.L. Jeter; H.F. Clark, A Delayed Incubation Membrane Filter Test for Coliform Bacteria in Water, American Journal of Public Health, Nov. 1955

e. J.H. Standridge, J.J. Delfino, Effect of Ambient Temperature Storage on Potable Water Coliform Population Estimations, Applied and Environmental Microbiology, Nov. 1983

C. Proposed Solution

Changes to be made on page(s): _____ of the (X - one of the following):

_____	2011 PMO	_____	2011 EML
_____	2011 MMSR	X	2400 Forms
_____	2011 Procedures	_____	2011 Constitution and Bylaws

Edit 2400m Dairy Waters as follows

1. Laboratory Requirements

e. Transit time does not exceed ~~30~~ 48 hours
f. Samples examined within ~~30~~ 48 hours of collection or within 2 hours of receipt (item 1d)

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